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Exhibit 1 Sanofi-Aventis

ase 1.0	Quote (5)	The FDA were concerned about psychiatric side effects including suicidality in the original filing We have previously highlighted our safety concerns of depression and suicide risk in our Citi Investment Research report "Mission Acomplia CI", 9/2/06. Yesterday FDA briefing documents confirmed our suspicions: The approvable letter in 2006 was due to the FDA's "concern about Glan] increased frequency of psychiatric adverse events, including suicidality". Concerns over psychiatric events, suicidality, seizures and Glandefined neurological symptoms triggered the approvable letter in February 2006.	Independent blinded assessment shows Zimulti doubles Suicidality As we forecast Zimulti (as it is now known, after the FDA felt that Acomplia would mislead patients into believing they would reach their therapeutic target) increases the risk of suicidality by double, according to an independent blinded analysis requested by the FDA. The odds ratio for suicidality in all clinical trials is a statistically significant 1.9x [95% CI 1.5-2.3], (Figure 1), and is 1.8x in obesity trials. The centire clinical trial database shows 2 cases of completed suicide whilst taking Zimulti. As of May 11, 2007 FDA received 15 reports of suicidal ideation in the post-marketing setting.	Roughly 50% of the subjects in the rimonabant and placebo groups withdrew early from the trials, with more rimonabant subjects doing so due to depression, anxiety, mood alteration with depressive symptoms, and the need for antidepressant medication. Given the lack of systematic follow-up of these subjects and Zimulti's long half-life (~16 days on average), the FDA suggested to the panel that the results of the above analyses should be viewed as incomplete at best and at worse as an underestimate of Zimulti's risk for suicidality.	Double Psychiatric side-effects on trial despite psychiatric exclusion criteria As we had forecast, psychiatric adverse events were worse too. The risk of psychiatric side effects is 60% greater on Zimulti 20mg vs. placebo On market safety data shows "6 reports of psychotic behaviour (including a man who tried to strangle his daughter)" Post- marketing data also shows "5 cases of aggression, including a man who tried to beat his wife".	Triple the risk of Neurological Side Effects in diabetics Neurological events occurred 70% more frequently with Zimulti, (3 times higher in diabetic trials 8 cases of seizure in ongoing trials (6 on prinonabant vs 2 on placebo). Movement disorders were 18x more frequent in the rimonabant 20mg group vs placebo, these include potential Parkinsonian symptoms linked to the drugs mechanism of action. As forecast memory loss and cognitive disorder were also seen.	The FDA state that the 80% increase in accidents on RIO trials (contusions, concussions, falls, traffic accidents and whiplash) from 3.8% on Coplete to 6.9% on Acomplia 20mg could be caused by the increased cognitive and neurological impairment that occurred with Zimulti . Risk — Benefit Ratio Skewed To Downside Considering modest weight loss and some weight regain, along with the concern of widespread use despite a risk management program, the risk-benefit is unclear. This could lead to a mixed at best Panel and an approvable letter while the FDA waits for risk benefit proof from the 17,000 patient mortality trial (CRESCENDO) due in 2010	The FDA's question to the Advisory committee:
s		The FDA were We have previt I", 9/2/06. Yest [an] increased ill-defined neur	Independent bl As we forecast 2 therapeutic targe odds ratio for s entire clinical t suicidal ideatio	Roughly 50% of to depression, is systematic follor above analyses	Double Psychia As we had forec placebo On m marketing data a	Triple the risk Neurological ev rimonabant vs potential Parkim	The FDA state t placebo to 6.9% Risk – Benefit Considering mo benefit is unclea	The FDA's ques
Did Analyst Discuss FDA's Suicidality	Findings? (4)	Yes						
	Title (3)	FDA states Zimulti (Acomplia) doubles suicidality rate in Advisory Committee briefing documents						
Report	Analyst ¹ (2)	Citigroup						
	Date (1)	6/12/07						
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Exhibit 1 Sanofi-Aventis Analyst Comments on June 11, 2007 and June 12, 2007 About the Safety of Rimonabant

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		Quote (5)	 1a. Do you believe that rimonabant causally increases the incidence of: • Suicidality? • Psychiatric adverse events other than suicidality? • Neurological adverse events other than seizures? • Seizures? 1b. If yes to the above, do you believe that the increases are, or will be, clinically important? 2a. Do you believe that the currently available data sufficiently characterize rimonabant's safety profile? 2b. If no, please discuss what additional data should be obtained. 	 3a. Based on the currently available data, do you believe rimonabant has a favorable risk-benefit profile and should be approved for the indication of weight management in individuals with a body mass index of > 30 kg/m2 and > 27 kg/m2 when accompanied by at least one comorbid condition? 3b. If no, please explain why and discuss what additional information the sponsor could obtain that might improve rimonabant's risk-benefit profile. 3c. If yes, are there specific labeling recommendations that you have 	FDA briefing books raise concerns over Zimulti adverse events. The FDA briefing books have raised concerns over serious adverse events associated with Zimulti. Given other therapeutic options for weight loss, and a lack of data to support clinical outcomes (mortality etc.), nonapproval is clearly a possibility	FDA briefing books raise concern over infrequent but serious adverse events. As anticipated, the briefing books conclude that Zimulti has Xenical like efficacy but a far more questionable adverse event profile than previously assumed, with an increased risk of suicidality (HR 1.9), psychiatric events (HR =1.9) and serious neurological events (HR = 1.7 but 3.1 in diabetic patients). In the absence of clinical trial data or evidence supporting a clinical outcome benefit there remains significant risk (>30%) that the FDA panel does not recommend Zimulti for approval.	Best case scenario appears to be approval with significant risk warnings. Approval with boxed warnings highlighting the potential risk of neurological adverse events and suicidality will limit revenue potential Relative to expectations, there appears to be a significant risk of Zimulti non-approval, based on FDA briefing books. With the efficacy of Zimulti (Acomplia) relatively well understood, the FDA panel was always likely to focus its attention of the safety of Zimulti, given the known CNS adverse events witnessed in phase III studies and from post marketing surveillance data in Europe. Based on the draft questions and the data published within the briefing books, we believe there is a significant (>30%) probability of non approval. The most likely outcome, in our view, is a recommendation for approval with substantial risk warnings and a high likelihood of a boxed warning or patient register
Did Analyst Discuss FDA's	Suicidality	Findings? (4)			Yes		
		Title (3)			FDA briefing books highlight Zimulti safety	COLCELLS	
	Report	Analyst (2)			Deutsche Bank		
		Date (1)			2. 6/11/07		
					[~		

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Exhibit 1 Sanofi-Aventis

	Quote (5)	FDA panel set to answer three questions The FDA panel members (scheduled for June 13, 2007) will review the clinical trial data supporting the NDA for Zimulti with three specific questions in mind.	Question 1: FDA panel likely to conclude that Zimulti increases the incidence of CNS adverse events 1a. Do you believe that rimonabant causally increases the incidence of: • Suicidality? • Psychiatric adverse events other than suicidality? • Neurological adverse events other than seizures? • Seizures? 1b. If yes to the above, do you believe that the increases are, or will be, clinically important?	Suicidality: Dr Kelly Posner's group at Columbia university conclude that the odds ratio for suicidality was 1.9 with a 95% CI of 1.1 – 3.1 however when limited to the obesity studies the odds ratio was 1.8 (95% CI; 0.8 – 3.8). In answering part B, it is worth noting that most cases were suicidal ideation (passive thoughts about wanting to be dead or active thoughts about killing oneself, not accompanied by preparatory behavior) and the clinical relevance of this will likely form a significant part of the panels debate/discussion. Psychiatric adverse events other than suicidality: There is little doubt that the FDA panel will conclude that there is an increased incidence in psychiatric adverse events other than suicidality. Anxiety (6.02% versus 2.50%), depression (3.4% versus 1.44%) are clinically important, in our view	Neurological adverse events other than seizures there is also little doubt that the FDA will conclude that there is an increased incidence in neurological disorders	Seizures: While a full statistical analyses of the seizure data will be provided during the FDA presentation, there would appear to be a slight increase in seizure frequency (0.26% versus 0.18%). Question 2: Split vote anticipated, but FDA panel likely to conclude that there is sufficient safety data on which to base an approval decision. 2a. Do you believe that the currently available data sufficiently characterize rimonabant's safety profile? 2b. If no, please discuss what additional data should be obtained. In our view, there is likely to be a split panel in answering this question.	In our view, there is likely to be a split panel in answering this question. Clearly the risk associated with some of the more serious, but less frequent neurological adverse events cannot be satisfactorily quantified, given the small number of patients included within clinical trials. Given their infrequent nature, these adverse events are unlikely to be better quantified from the currently ongoing clinical trials, and thus there is little merit in delaying an approval decision to review data from such trials. These adverse events will be better monitored in post marketing surveillance studies potentially aided by a patient register, similar to that originally used by Roaccutane and Bosentan.
Did Analyst Discuss FDA's Suicidality	Findings? (4)						
	Title (3)						
Report	Analyst ¹ (2)						
	Date (1)						

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Exhibit 1 Sanofi-Aventis

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	· ·	Quote	(5)	Question 3: Approval dependant upon Sanofi convincing the panel that intentional weight loss will likely lead to mortality henefits that outweigh safety concerns.	3a. Based on the currently available data, do you believe rimonabant has a favorable riskbenefit profile and should be approved for the indication of weight management in individuals with a body mass index of > 30 kg/m2 and > 27 kg/m2 when accompanied by at least one comorbid condition? Such that is a possible in why and discuss what additional information the sponsor could obtain that might improve rimonabant's risk-benefit	product in short term studies (<2 years), with weight loss as the primary endpoint, it is far harder to quantify the clinical benefits associated with losing weight.		Clinical trial data from the RIO studies data concludes that Zimulti has an efficacy profile not too dissimilar to that of currently approved obesity agents however it does appear to have a more serious adverse event profile. On that basis the FDA could conclude that Zimulti has an	weight loss is associated with a mortality benefit and that this predicted mortality benefit outweights the serious adverse events caused by Zimulti use. With no data or clinical studies to demonstrate that intentional weight loss is associated with a mortality benefit, Sanofi may struggle to	COUVINCE LIET DANS OF LIMITAL STREET COURTS.	If recommended for approval, it is likely that Zimulti will have a boxed warning possibly highlighting the rare neurological adverse events that have been witnessed to date and the increased suicidality risk that has been observed. It is also highly likely that a patient register will be required.	When assessing the approvable nature of Zimulti, the FDA will clearly base their decision on the overall risk/ benefit profile	Acomplia/Zimulti: FDA has no issues with efficacy. Sanofi are asking for a diabetes indication as well as an obesity indication. FDA has potential issues with suicide ideation and neurogical events. Key issue: Will FDA view suicide risk bearable given benefits and risk management plan that	Sanoti suggests? On balance, we think committee will vote positive and advise Buy			
Did Analyst	Discuss FDA's Suicidality	Findings?	3										Yes				
		Title	(3)										Acomplia Efficacy fine. Possible	suicide issue. On balance, drug still likely to be	approved. Buy ahead of meeting.		
	Report	Analyst 1	(2)										Dresdner Kleinwort				
		Date	Ξ										6/11/07				
	•	-											3.				

Exhibit 1 Sanofi-Aventis

Sase 1.0	Quote	(5)	We are mainly concerned about the FDA view on the suicide risk. However we note it is mainly in ideation (39/6802 cases on 20mg vs 13/2909 on placebo) not on suicide attempts which are better only 4/6802 vs 7/2909 on placebo. Given this and the fact that the 7 obese studies taken together did not show a higher risk (only when pooled with the schizophrenia and smokers studies) we believe on balance this is manageable. On balance, we still think FDA comittee are likely to vote to approve the drug with a possible black box warning on suicide risk and a contraindication in any high risk populations for neurogical/psychiatric conditions. While the CNS side effects do seem to be significant, we think on balance they should be manageable.	We believe a black box warning may be possible, but would not overly dent the long term commercial impact of the drug if properly managed.	► To summarise, we believe that psychiatric/neurological side effects seen with Acomplia 20mg are "clinically important" (question 1b), including an increase in suicidality which appears no higher than SSRI antidepressants. However, we still believe the balance of benefits versus risks favours Acomplia (question 3a). ► We still anticipate a requirement for a black-box warning on psychiatric and neurological side effects excluding patients with a history of depression (40% of the cases of suicidality) together with tight risk-management and a pharmacovigilance programme.	Question 1a. Do you believe that Rimonabant causally increases the incidence of:	 Suicidality? YES The "suicidal risk" follows the same trend (risk x2.0 vs placebo) as psychiatric events, at 0.64% for Acomplia patients vs 0.32% for placebo. 	There were more suicide attempts in the placebo group (0.24% vs 0.14% on Acomplia 20mg), more "suicidal ideation" with Acomplia 20mg (0.57% vs 0.45% placebo). More than 40% of the depressive events and suicidality seen with Acomplia and placebo occurred in patients with prior history of depressive disorders.	The increase in suicidality is similar to that of SSRIs. To take an analogy with anti-depressants, the FDA already asked an advisory committee to review the suicidal behaviour risk with SSRI anti-depressants in 2004. All drugs were kept on the market with a black-box warning highlighting the increasing risk of suicidal thinking and behaviour (suicidality) in children and adolescents. According to the black box (review of 24 trials involving 4,400 patients) the average risk is twice the placebo risk: i.e. 4% vs 2% (no suicide occurred during the trials), a similar increase in risk of as seen with Rimonabant above (x2.0) but with smaller numbers (+0.32% for Acomplia vs +2% for SSRIs).	• Psychiatric adverse events other than suicidality? YES There are 1.9x more psychiatric adverse events with Acomplia 20mg than with placebo in obese patients. This can be explained by the drug's mecanism of action.
Did Analyst Discuss FDA's Suicidality	Findings?		Si Ti II &	<u> </u>	Yes o	<u> </u>	• F a	E & &		• 🗕
	Title	(3)			Acomplia: in the shoes of an FDA panel member					
Report	Analyst 1	(2)			Exane BNP Paribas					
	Date	<u>(T)</u>			4. 6/12/07					

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		Quote	(5)	• Neurological adverse events other than seizures? YES There are 1.9x more neurological adverse events with Acomplia 20mg than with placebo in obese patients. This can be explained by the drug's	mecanism of action. It is worth pointing out that there are no difference in multiple sclerosis cases vs placebo (some bears had highlighted this risk): 0.05% for both Acomplia and placebo.	• Seizures? NO Seizures are also closely watched by the FDA, as there seems to be a signal in diabetic patients (no difference in the overall population), but with	a very small numbers of patients. The FDA seems relieved by the low rates observed vs what preclinical data hinted at in terms of proconvulsant role.	Question 1b. If yes to the above questions, do you believe that the increases are, or will be, clinically important? YES	We believe the increases are potentially clinically significant, but did not translate into a difference in death rates: 0.15% with Acomplia 20mg vs 0.12% placebo.	Question 2a. Do you believe that the currently available data sufficiently characterize Rimonabant's safety profile? YES	Although discontinuation rates are high within the RIO-trials, we believe the data pool is enough to characterise Rimonabant's safety nrofile.	- Discontinuation rate at 1 year (pooled RIO data, re-adjudicated by the FDA) = 55.2% for Acomplia/Zimulti 20mg vs 50.9% for placebo i.e., Acomplia/Zimulti 4.3% higher than placebo. In the published data, Acomplia/Zimulti 20mg was usually 1-4% lower than placebo. - Discontinuation rate due to adverse events (pooled RIO data, re-adjudicated by the FDA): Acomplia usually 5-10% above placebo as reported by SAN. In the FDA errata, the rate is 9.9%, i.e., at the high-and of the rance.		This is where the Avandia issue does not help SAN, as a risk could be that the FDA would want to see the phase IV trials data (and in particular the CRESCENDO trial scheduled for completion in 2010) prior to approving the drug, not after.	Question 2b. If no, please discuss what additional data should be obtained. NR	Question 3a. Based on the currently available data, do you believe Rimonabant has a favourable risk-benefit profile and should be approved for the indication of weight management in individuals with a body mass index of > 30 kg/m2 and > 27 kg/m2 when accompanied by at least one comorbid condition? YES	Question 3b. If no, please explain why and discuss what additional information the sponsor could obtain that might improve Rimonabant's riskbenefit profile.
Did Analyst	Suicidality	Findings?	3														
		Title	(3)														
	Report	Analyst ¹	(2)														
		Date	Ξ														

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Exhibit 1 Sanofi-Aventis

Case :	1:07	-cv-	102	79-GBD-	-FM Doci	ıment 188-1	File	d 04/30/12	Page 7 o	† 141
		S)	Question 3c. If yes, are there specific labelling recommendations that you have?	With clinically significant weight loss (48-51% of patients losing more than 5% of their weight vs 19-20% on placebo, 25-28% losing more than 10% vs 7-9% for placebo) as well as an 8% increase in HDL-C, 12% decrease in triglycerides and 0.7% reduction in HbA1c in overweight and obese subjects with type 2 diabetes, we believe the risk/benefit of Acomplia remains favourable.	We are anticipating a requirement for a black-box warning on psychiatric and neurological side effects together with a tight risk-management and pharmacovigilance programme. As in Europe, Rimonabant should be contraindicated for patients with a prior history of depression and epilepsy. A risk management plan has been submitted by SAN, similar to (if not stronger than) the one put in place in Europe. It involves medical education, communication to journalists, physician education and a prescription survey.	n.a.	- The FDA has published briefing documents from 13 June advisory committee They include a complete analysis of suicidal tendencies attributable to rimonabant .	The FDA website has published briefing documents to be used as the basis for debate by the advisory committee on 13 June. They reveal the points on which the FDA has focused and the reasons for the delay since the approvable letter on 17 February 2006 This particularly involves the question of suicidal tendencies observed in some patients. The CHMP (European equivalent of advisory committee) in its report on rimonabant, stated that it was satisfied that only one suicide was observed in RIO trials and that it was not related to the product.	However, the FDA is concerned about the drug's mechanism, and has asked sanoff-aventis to provide additional information on patients, which has then been handed on to a specialist at Columbia university, who has rated the patients on a scale of suicidal tendencies. After analysis, 39 patients presented suicidal ideation, in the rimonabant 20 mg group (out of 6,800 patients) vs. 13 for the placebo (out of 2,900 patients). A statistical analysis shows a twofold increase in the risk of suicidal ideation. This difference is the main issue that the drug will face on Wednesday.	Implications: Questions addressed to experts focus particularly on suicidal tendencies. However, besides the absence of cases of actual suicide with the product, there were four cases of suicide attempts in patients taking rimonabant, vs. seven with the placebo. The FDA analysis with the product, there were four cases of suicide attempts in patients taking rimonabant, vs. seven with the placebo. The FDA analysis pushes statistical subtleties to the limit. We cannot be sure that committee experts, who are specialists in endocrinology and hence used to dealing with products with significant side effects (metformin, etc.) will be equally sensitive to this point. However, in a difficult context after the media hype on the side effects of Avandia (GSK), the verdict could go either way in our view, although logically the product should be approved.
Did Analyst Discuss FDA's	Suicidality	(4)				n.a.	Yes			
	, att	(3)				Robust product pipeline raises outlook in wake of emerging generic competition	Suspense continues on rimonabant			
	Report	Allanyst (2)				IIR Group	IXIS			
	45.6	(1)				6/11/07	6/12/07			
	I	I				v.	9			

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Exhibit 1 Sanofi-Aventis

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S.	Quote	(5)	 FDA published briefing documents on Zimulti (formerly Acomplia) ahead of the July 13th panel (this Wednesday). Increased "suicidality" looks to be the major FDA concern. We now have a clear picture of Zimulti's difficult path to market. The risk that the drug could increase suicide rates is suspected but clinical data show no difference between Zimulti and placebo. However the FDA requested a deeper analysis of the side-effect data to identify how many patients experienced a potential signal - "suicidal ideation" defined as passive thoughts about killing oneself, not accompanied by preparatory behavior. This analysis, conducted over the last few months, has revealed a significant signal with a suicidality rate of 0.68% in the Zimulti 20mg arm versus 0.41% in the placebo arm. The FDA Advisory committee looks set to review this new data in detail with a two psychiatry experts added to the panel as guest voting members and a presentation by the psychiatry expert that undertook the suicidality analysis as a specific agenda item. On the positive side, the FDA does conclude that Zimulti gives "statistically and clinically meaningful weight loss", but must judge the risk-benefit with respect to the increased suicidality risk. It's a very close call. Risks to our rating We forecast US approval for Acomplia in H2 2007. US approval cannot be guaranteed and could be subject to further delay. Delays to Acomplia in the US would be damaging to the share price. 	Vesterday evening, the FDA published on its website the briefing document for Acomplia that will be presented to the advisory committee experts on 13 June. This chunky document (88 pages) is mainly devoted to the effects that rimonabant has on the central nervous system, its neurological and psychiatric side effects (e.g. depression, suicidal thoughts and behaviour, anxiety, exacerbation of multiple sclerosis flares). As far as we can remember, this is the first time that an obesity treatment (or a diabetes treatment) has been involved in such an in-depth review of side effects. After reading this document, as well as the accompanying letter, we think it is very difficult to tell what conclusion the advisory committee will draw. Without going into detail, the document is a group of statistical studies covering all of the clinical trials that Sanoff-Aventis has conducted with Acomplia (obesity, diabetes and smoking cessation), and also compiles pharmacovigilance data collected in Europe. The experts are bound to focus on the risk of suicide that seems to be linked to taking Acomplia. The FDA does not hide the fact that it is concerned about the consequences that taking the product has on central cannabinoid receptors.
Did Analyst Discuss FDA's Suicidality	Findings?	(4)	Yes	Yes
	Title	(3)	FDA Focus on Zimulti Suicidality Risk- ALERT	SANOFI- AVENTIS - Acomplia/Zimulti: a 'neurological' dossier that is a first for an obesity treatment - 12th June, 2007.
Report	Analyst 1	(2)	JP Morgan	Raymond James Euro Equities
	Date	(1)	6/11/07	6/12/07
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Exhibit 1

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	Quote (5)	74 cases of suicidality were seen in clinical trials, including 54 in the treated arms and 20 in control groups. There is a table that may be seen as reassuring — showing the severity of the cases reported in patients taking rimonabant as there were more suicide attempts under placebo. One study, METATRIAL, introduces a clear bias into the data as 5 of the 7 patients taking the placebo who attempted to kill themselves were schizophrenics taking haloperidol. The odds ratio for incidence of suicidality — which includes actual suicides, suicidal behaviour and thoughts — came to 1.9 under rimonabant all studies combined with statistical significance, and 1.8 for the obesity studies alone. Updating the clinical dossier using the trials underway added another 17 cases (11 under rimonabant and 6 under placebo), including one suicide in the STRADIVARIUS study (which comes on top of the one seen in the RIO North America study, with 5mg) and two suicide attempts in CRESCENDO.	The pharmacovigilance data is also impressive, but we would point out these documents intended for the panel of experts involved in such a committee meeting have to be handled very carefully. The aim is to target side effects rather than to give a balanced analysis of the drug's benefit/risk profile In the past, we have often been led astray by the contents of a briefing document and the alarming tone of the expert in charge of summarising a compound's side effects. We will wait to see the final vote of the 14 experts tomorrow.	Among the potential catalysts, Plavixs US patent should be upheld, Acomplia should be approved in the US and a number of Phase III trial results are to be announced shortly at scientific meetings	The FDA has released early the documents for its Advisory Committee meeting on 13 June. They highlight the efficacy of rimonabant 20mg, but also focus very much on the CNS risks (depressive disorders, suicidal thoughts, anxiety), which is the reason behind the Feb. 06 approvable letter. The FDA requested a more in-depth analysis of these CNS risks including suicidal behaviour. Overleaf is our analysis of the Committee background: half have no background in obesity and we estimate that, based on their recent publications, etc, the other half could be split.	We ultimately expect the experts to recommend rimonabant for approval , albeit in very specific populations with the highest risk, like obese/overweight patients with type 2 diabetes. We also expect the experts to vote in favour of a serious warning about the CNS risks (black box on suicidal risk?) .
Did Analyst Discuss FDA's Suicidality	Findings? (4)			Yes		
7.6	(3)			FDA documents released earlier, highlight CNS side-	effects	
Report	Analyst (2)			Societe Generale		
	Date (1)			6/12/07		
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	Quote	(5)	FDA posted its questions for its Advisory Committee on Wednesday. They have specifically three questions: 1) Do you believe that rimonabant causally increases the incidence of: i) suicidality?; ii) psychiatric adverse events other than suicidality?; iii) neurological adverse events other than seizures?, iv) seizures? If yes to the above, do you believe that the increases are, or will be, clinically important? 2) Do you believe that the currently available data sufficiently characterize rimonabant's safety profile? If no, please discuss what additional data should be obtained. 3) Based on data currently available data, do you believe rimonabant has a favourable risk-benefit profile and should be approved for the indication of weight management in individuals with a 8MI >30 and >27 when accompanied by at least one comorbid condition? If no, please explain why and discuss what additional information the sponsor could obtain that might improve rimonabant's risk-benefit profile. If yes, are there specific labeling recommendations that you have?	The FDA does not question at all the efficacy of the product but how side-effects could be managed in practice. The FDA explicitly recognizes that the safety database for rimonabant is large and growing and that the company has initiated large clinical trials to evaluate the effect in reducing cardiovascular morbidity (e.g. CRESCENDO, which has already recruited 8,000 patients on the 17,000 planned). We think the panel will vote in favour of a very specific indication (perhaps more restrictive, to only type 2 diabetic patients) WITH a warning on psychiatric side-effects.	☐ No dispute on weight-loss efficacy ☐ In the Briefing documents released by the FDA ahead of Wednesday's meeting of an expert Advisory Committee show that the FDA staff note The standard (Acomplia/Zimulti) 20mg results in statistically and clinically significant weight loss. It is not clear from our first look at the documents whether the FDA staff support a diabetes label, which we expect is unlikely to be granted.	□ Clear safety concerns; further data may be requested Although two cases of suicide of rimonabant patients were recorded, there may not be enough evidence to suggest this is due to the drug. However the FDA staff signal rimonabant is associated with higher risk of suicidal ideation, psychological and neurological adverse events and seizures. The FDA could ask for a warning regarding use in patients with history of psychiatric illness, will likely ask for further safety data, although this may not prevent (restricted) approval.	☐ Clean positive recommendation would be good for the stock In our view, a positive recommendation by the AdCom for approval in weight loss would be positively received by the market, provided that debate and uncertainty relating to suicide risk is limited.	
Did Analyst Discuss FDA's	Suicidanty Findings?	(4)			Yes			
	Title	(3)	The FDA has specifically three questions for its Advisory Committee		Acomplia AdCom briefing documents set to stimulate debate			
£	Report Analyst ¹	(2)	Societe Generale		UBS Investment Research			
	Date	(1)	6/12/07		6/11/07			
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Exhibit 1

Analyst Comments on June 11, 2007 and June 12, 2007 About the Safety of Rimonabant Sanofi-Aventis

	Quote	(5)	<u> </u>	As outlined in the approvable letter for Acomplia/Zimulti (rimonabant) from February 2006, the FDA is concerned about the increased frequencies of psychiatric adverse events, including suicidality, an ill-defined constellation of neurological signs and symptoms, as well as seizures. Although only two completed suicides during the clinical trials by participants treated with Acomplia were reported it appears that according to an analysis conducted by a team of the University of Columbia 'possible and/or definitive cases of suicidality' did outnumber the cases for those on placebo vs. active treatment by three to one. As such we believe that there is an increase risk that the FDA advisory committee meeting which is scheduled for tomorrow, 13 June, is advising against approving Acomplia in the US.	
Did Analyst Discuss FDA's Suicidality	Findings?	(4)		Yes	10
	Title	(3)	Cessation of coverage	FDA advisory committee briefing material does not bode well for US approval	Fotal Number of "Yes":
Report	Analyst 1	(2)	UBS Investment Research	West LB Equity Research	Tot
	Date	(1)	6/12/07 UBS Inves Resec	6/12/07 West LB Equity Research	
				11	

Notes and Sources:

This exhibit includes all uniquely-titled English-language, company-specific, non-technical reports issued during the period that NERA was able to obtain from counsel

or purchase from Reuters Knowledge or Thomson Investext. Exhibit does not include any analyst reports published on 6/11/07 prior to the release of the FDA briefing documents.

¹ Excludes Prudential who published a report on 6/12/07 to state they are terminating coverage of Sanofi Aventis.

	Briefing	Page	(9)	p. 26	p. 26, 27, Table 14
2007 ³		Section ⁴	(2)	Clinical	Clinical
The FDA's Briefing Document Posted on June 11, 2007		Quote	(4)	"A total of 1201 patient-narratives were assessed in a strictly blinded manner by the Columbia University group. Ninety-one (91) cases were classified as either possibly (Columbia categories 5, 6, or 9), or definitely (Columbia categories 1, 2, 3, or 4) suicidal; this includes 5 cases which occurred on haloperidol active treatment."	"The tables below summarize all possible and/or definite cases of suicidality as adjudicated by the Columbia University group for all completed studies as of 18 December 2006. A total of 13 studies were used in the analyses: Study ACT4389 (which had no 20 mg rimonabant treatment group) and study EFC4798 (which had no placebo treatment group) and study DRI5747 (which did not have a clinical study report completed as of the cut-off date) were excluded from the analyses. Studies EFC4743 and EFC4796 re-randomized patients during a maintenance phase treatment after the first randomized treatment. Only data from the first randomization were used in the analyses.
	Transcript	Page	(3)	p. 283, Slide 46	p. 284- 285, Slide 48
e 13, 2007 ²		Speaker	(2)	Dr. Egan	Dr. Egan
The FDA's Advisory Committee Presentation on June 13, 2007 ²		Quote	(1)	"A total of 1201 patient narratives were prepared by Sanofi and submitted to Dr. Posner's group for a blinded analysis. The analysis identified 91 cases of either definitely or possibly suicidal. This included five cases which occurred on haloperidol active treatment. The majority of cases were assigned to Columbia category 4 which is suicidal ideation. Of the 91 cases, 64 were considered to be suicidal ideation. This included 14 cases occurring on placebo, 10 on rimonaly and 5 and 4 loar rimonaly and 20 are imported 10.	"A total of 13 studies were used in our analyses, RIO North America and EFC 4796, which was a large smoking-cessation trial, re-randomized patients during a maintenance phase after the randomized treatment. Only data from the first randomization was used in the primary analysis. The control group employed for study EFC 4796 was rimonabant 5 mg as there was no placebo group in the first randomization. Sensitivity analyses were performed both including all suicidality events and ignoring the second randomization as well as excluding studies with a second randomization.
				_	6

Case 1:07-cv-10279-GBD-FM Document 188-1 Filed 04/30/12 Page 13 of 141

Exhibit 2 Sanofi-Aventis

The FDA's Advisory Committee Presentation on June 13	3, 2007 2		The FDA's Briefing Document Posted on June 11, 2007	07 3	£
Ouote	Speaker	Transcript Page	Quote	Section ⁴	Briefing Page
	(2)	(3)	(4)	(5)	(9)
Thus, the total number of suicidality cases contributing to the analyses is 74, 46 on rimonabant 20 which included: four suicide attempts, 39 suicidal ideations and 3 not enough information, non fatal; 8 cases of suicidality on rimonabant 5 mg, 1 preparatory act toward imminent suicidality on rimonabant 5 mg, 1 preparatory act toward imminent suicide, 6 suicidal ideations and 1 not enough information, fatal; and 20 cases on placebo, 7 suicide attempts which, I should point out, 3 occurred in the schizophrenic trials and 3 in the alcoholic trials and 1 in the smoking-cessation trial and 13 cases of suicidal ideation."			Thus, the total number of suicidality cases contributing to the analyses is 74 (20 on placebo, 8 on rimonabant 5 mg, and 46 on rimonabant 20 mg)." See Table 14: Columbia Classification of Suicidality Events Table 14 shows that of the 46 suicidality classifications on 20 mg rimonabant, 4 were suicide attempts, 39 were cases of suicidal ideation, and 3 were classified as not enough information (non-fatal). Of the 8 cases classified for suicidality on 5mg rimonabant, 1 prepatory act toward imminent suicide, 6 suicidal ideations, and 1 not enough information (fatal). On placebo, there were 7 classifications of suicide attempt and 13 cases of suicidal ideation.		
			"Fourteen studies contributed to the analysis which had a total of 74 suicidality cases (1st randomization): 20 in placebo, 8 in 5 mg rimonabant and 46 in 20 mg rimonabant."	Statistical	p. 7
"The odds ratio for the incidence of suicidality, rimonabant 20 versus placebo for all of the studies contributing to the analysis is 1.9 which is of nominal statistical significance."	Dr. Egan	p. 285- 286, Slide 49	"The overall odds ratio (CI) for the incidence of suicidality: 20 mg versus placebo for the cases indicated above was 1.9 (1.1, 3.1) (Figure 4)."	Clinical	p. 28, Figure 4
"Here we are looking just at the 7 obesity studies so you can forget about that smoking-cessation and whether or not we should have used 5 mg as our control arm. You can see our point estimate has changed very little, still 1.8."	Dr. Egan	p. 286, Slide 50	"When limited to the 7 obesity studies, the odds ratio for incidence of suicidality: 20 mg versus placebo was 1.8 (0.8, 3.8) (Figure 5)."	Clinical	p. 28, Figure 5
"I should point out that sensitivity analysis, adding the second randomization events to the first randomization, resulted in an exact te[s]t odds ratio of 1.93."	Dr. Egan	p. 286	"For sensitivity analysis, the 2nd randomization events were added to the 1st randomization. The exact test OR [95% CL] was 1.93 [0.92, 4.28]. The p value was 0.11."	Statistical	p. 12

	Briefing	Page	(9)	p. 30 - 31		
The FDA's Briefing Document Posted on June 11, 2007^3		Section ⁴	(5)	Clinical		
		Quote	(4)	"According to Sanofi-Aventis, in ongoing trials as of the December 18, 2006 cut-off date, data were available on 17 unblinded cases of suicidality - 11 on rimonabant 20 mg and 6 on placebo. The rimonabant 20 mg cases included 1 completed suicide, 1 self-injurious ideation, 8 suicidal ideations, and 1 depression suicidal; the placebo cases included 2 suicide attempts and 5 suicidal ideations. It should be noted that the Division had also received 2 additional reports during this time periodone of "homicidal ideation" in a subject receiving rimonabant 20 mg in study PMC_0172 and one of suicide attempt in a subject receiving rimonabant 20 mg in study PMC_823.	It should be noted that in the entire rimonabant clinical trial database, there have been 2 completed suicides – one in RIO North America in a subject taking rimonabant 5 mg and one in the ongoing study STRADIVARIUS in a subject taking rimonabant 20 mg."	
	Transcript	Page	(3)	p. 286- 287, Slide 51		
13, 2007 2		Speaker	(2)	Dr. Egan		
The FDA's Advisory Committee Presentation on June	•	Quote	(1)	"To date, four completed suicides have been reported, 3 in the entire rimonabant clinical-trial database and one postmarketing. All of the cases of suicide occurring during rimonabant clinical trials have occurred in subjects on active treatment, none on placebo."	"To briefly summarize these cases: in RIO North America, a 63-year-old gentleman taking rimonabant 5 mg; in STRADIVARIUS, which is an ongoing study; a 36-year-old male on rimonabant 20 mg; and, in CRESCENDO, a 77-year-old male on rimonabant 20 mg. I know that the sponsor highlighted this as a case where the gentleman had stopped rimonabant a week before he committed suicide. Just to clarify that, that is absolutely true and the reason he stopped it is that the IRB at that investigation site insisted that a letter be circulated warning of the risk between rimonabant and suicidality; postmarketing, a 33-year-old male on rimonabant 20. Again, the details on this case are sketchy but we do know that this gentleman had a BMI of less than 20."	[Sanofi's June 13, 2007 sponsor presentation shows that the Company learned of the CRESCENDO suicide on 22 May 2007 and learned about the completed suicide in postmarketing on 28 May 2007. See Clinical Safety presentation slides by Dr. Paul Chew, slides MM-111 - MM-113.]
				9		

∞ d.
Statistical
"Compared to placebo, 20 mg rimonabant statistically significantly increased suicidality based on analyses both of incidence rates and person-years."
suicidal ideation, the so-called semi-starvation neurosis? Subjects who experience significant weight loss may exhibit psychiatric disorders such as depression, anxiety and suicidal ideation Is the association due to chance? You can never rule out chance but, again, is it chance in 9 of 13 studies? Or is the association causal? And we strongly believe that it is causal. We know that it is biologically plausible given the role of the endocannabinoid system specifically the CB1 receptor function in the central nervous system. After all, that is why the sponsor excluded depressed patients. We find a similar increase in the risk of depression in the clinical trials and suicidality is a symptom of depression. So it is not really surprising. In fact, it would have been more surprising if we didn't see it. So, in summary, our meta-analysis indicates an increased risk for suicidality, specifically suicidal ideation, in subjects taking rimonabant 20 mg versus placebo. There is an increase in relative risk of 80 to 100 percent and an increase in absolute risk of 0.3 percent."

Exhibit 2

Sanofi-Aventis

	Briefing	Page	p. 36 - 38,	1able 20			
2007 3		Section ⁴	Clinical				
The FDA's Briefing Document Posted on June 11, 2007 $^{\mathrm{3}}$		Quote	"Sanofi-Aventis submitted a periodic safety update report (PSUR) for the	time period June 19, 2006 to December 18, 2006. Kimonabant 20 mg oncedaily is currently approved in more than 30 countries in Europe, America, and Asia. It has been launched in 9 European countries, as well as in Argentina. From launch to 30 November 2006, the estimated worldwide post-marketing exposure was 78,610 treated patients, mainly in Germany and in the United Kingdom.	There were a total of 2362 adverse reactions associated with these 918 cases. The most frequently reported adverse reactions were of gastrointestinal (209 medically confirmed; 320 consumer reports), nervous system (143 medically confirmed; 154 consumer reports) or psychiatric (308 medically confirmed; 169 consumer reports) origins. The most frequent adverse reactions within these categories are summarized below: • Gastrointestinal adverse reactions: nausea (47.4%), diarrhea (16.8%), and vomiting (10.2%)	 Psychiatric adverse reactions: anxiety (10.7%), depressed mood (10.7%), depression (10.3%), and insomnia (7.3%) Nervous system adverse reactions: dizziness (27.6%), headache (17.8%), paresthesia (5.7%), tremor (5.1%), somnolence (4.4%), amnesia (4.0%), and disturbance in attention (3.7%) 	 Post-marketing data reveal 6 medically confirmed spontaneous reports of suicidal ideation and 3 consumer reports."
	Transcript	Page	p. 293,	Slide 61			
, 13, 2007 ²		Speaker (2)	Dr. Egan				
The FDA's Advisory Committee Presentation on June 13, 2007 $^{\mathrm{2}}$							

	Briefing	Page	(9)	p. 38	p. 3
2007 3		Section ⁴	(2)	Clinical	Statistical
The FDA's Briefing Document Posted on June 11, 2007^3		Quote	(4)	"The Division of Metabolism and Endocrine Products has been maintaining a log of all adverse event reports submitted to the Agency by Sanoff-Aventis. As of May 11, 2007, the Division had received 15 reports of suicidal ideation associated with rimonabant use in the post-marketing setting. Other reports of note are 4 reports of delusional symptoms, 6 reports of psychotic behavior (including a man who attempted to strangle his daughter), and 5 reports of aggression (including a man who beat his wife.)"	"The incidence of suicidality – specifically suicidal ideation – was higher for 20 mg rimonabant compared to placebo."
	Transcript	Page	(3)	p. 294, 296, Slide 63	p. 297 - 298, Slide 64
13, 2007 2		Speaker	(2)	Dr. Colman	Dr. Egan
The FDA's Advisory Committee Presentation on June 13, 2007^2	•	Quote	(1)	"These are data that we just obtained within the last week and, in some cases, actually yesterday. But, what we wanted to do was look and see what rimonabant looked like compared to the two other weight-loss drugs that had been around for 7 or 8 years So, we focused on that. But what this shows you, and I will just remind you that rimonabant, the approval began around this time last year. Sibutramine was approved in Europe in 1990, and orlistat was approved in 1998 in Europe. Again, these are data from the EMEA, postmarketing data spontaneously reported. We wanted to know how many cases of suicidal ideation the EMEA had for these compounds. Again, orlistat has been on the market over there since 1998. They have 14 cases of suicidal ideation. Sibutramine has been on the market in Europe since 1999. They have 15 cases of suicidal ideation. Rimonabant has not even been on the market for one year, almost one year, and they have 27 cases of suicidal ideation."	"The risks associated with the use of rimonabant include an approximate doubling in the risk of psychiatric adverse events specifically depression, anxiety, insomnia, and mood disturbances, an approximate doubling in the risk of suicidality, specifically, suicidal ideation, an increase in a constellation of neurological adverse events of unclear significance, a possible increase in seizure risk, an increase in nausea and vomiting vomiting—which we haven't really discussed today although it is the most commonly reported adverse events, and many of these risks appear more pronounced in diabetics—and as yet to be identified risks, and there will be further risks."
				6	10

To the Extent It Related to the Posner Coding, the Suicidality Information that the FDA Presented to Sanofi-Aventis Exhibit 2

the Advisory Committee on June 13, 2007 Had Been Made Public by the Agency on June 11, 2007

	Briefing	Page	(9)
20073		Section ⁴	(5)
The FDA's Briefing Document Posted on June 11, 2007		Quote	(4)
	Transcript	Page	(3)
ne 13, 2007 ²		Speaker	(2)

Notes and Sources:

Exhibit is ordered chronologically according to the Transcript to the AdCom meeting on June 13, 2007.

Findings 1-5 are based strictly on the Posner Codings.

Quotes included in exhibit are all those discussing suicidality from the Transcript to the AdCom Meeting and the related quote from the FDA Briefing Document, where available. Excludes mentions of suicidality in the context of requests for data, patients excluded from clinical trials, or discussions of the Posner suicidality categories.

² "NDA 21-888 Zimulti (rimonabant) Sanofi-Aventis" Wednesday, June 13, 2007 8:00 a.m. Transcript and slides, available at http://www.fda.gov/ohrms/dockets/ac/cder07.htm#DrugSafetyRiskMgmt

4 Refers to sections of the FDA Briefing Document, specifically, the "Statistical Review of Safety: Division of Biometrics II", and the "Clinical Review of Safety and Efficacy: Division of Metabolism and Endocrinology".

³ "FDA Briefing Document NDA 21-888 Zimulti (rimonabant) Tablets, 20 mg Sanofi Aventis Advisory Committee - June 13, 2007",

available at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4306b1-fda-backgrounder.pdf.

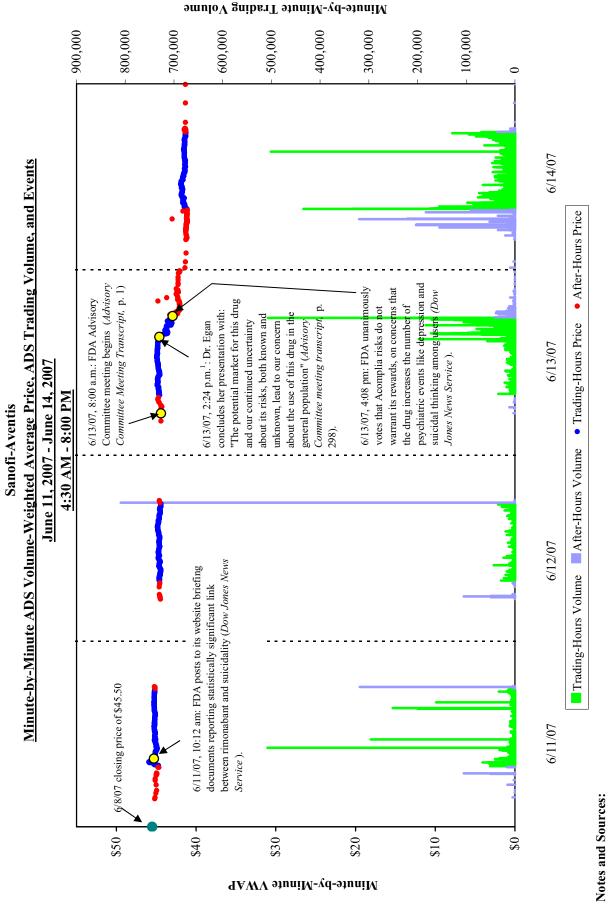


Exhibit 3.a

Data from TAQ, news from Factiva, Inc. Advisory Committee Meeting Transcript available at www.fda.gov. ¹ Time from Exhibit 4.

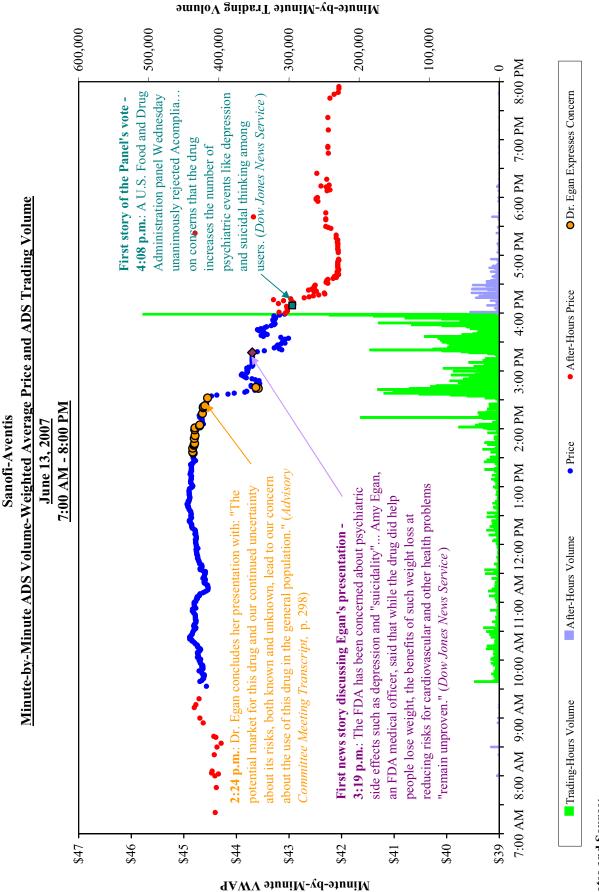


Exhibit 3.b

Data from TAQ, news from Factiva, Inc. Advisory Committee Meeting Transcript available at www.fda.gov. Notes and Source:

For Dr. Egan's statements expressing concern, see Exhibit 4.

	Transcript Page (1)	PPT Slide (2)	Time ¹ (3)	Quote (4)
1.	256-257	10	1:35 PM	This slide provides a summary of the overall exposure to rimonabant, 20 mg. As you can see, despite the overall large number of participants reported in the database. Approximately 1600 to date have taken the drug for one year and 441 subjects have taken it for two years.
				I point this out because many of you have expressed a concern about this being a chronic medication, a life-long medication. We are looking at data from 441 patients who have had two years of exposure to date.
2.	257	11	1:35 PM	Because of the varied nature of the data and the complexity of the datasets where adverse events were not all located within a single dataset but spread across three datasets, the analyses were difficult especially for safety signals where there were low event rates.
				For the purposes of today's analysis, we have focused on the largest of the three datasets, the adverse-event dataset, and for studies where subjects were re-randomized to a different treatment arm, such as 20 mg to placebo. or 5 mg to placebo, we focused only on those subjects who received the same treatment during the entire study.
3.	258	11	1:36 PM	This was done because of the long half-life of the drug, about 16 days on average, and the difficulty in assigning the adverse event to a particular treatment arm if it occurred after re-randomization, especially if it occurred during the first 90 days after rerandomization.
				I point this out because we know we are losing events by doing this. So you should view or [sic] analyses as conservative and an underestimate of the true risks associated with the use of rimonabant.
4.	261	16	1:40 PM	The vast array of [neurological adverse] events gave us a considerable sense of uneasiness. The neurological adverse events were not insignificant. They were responsible for 3.5 percent of the discontinuations due to adverse events from the RIO trials among rimonabant subjects versus 1.4 percent of placebo subjects.

	Transcript Page (1)	PPT Slide (2)	Time ¹ (3)	Quote (4)
5.	264	19	1:43 PM	As you can see, [cognitive disorders] category was driven predominantly by amnesia and memory impairment. But, again, the array of symptoms is worrisome; disturbance in attention, lethargy, disorientation, confusional state, cognitive disorder and memory loss.
6.	264-265	20	1:44 PM	What should be noted in this slide as well is the relative risk in RIO Diabetes which was a concern to us because of the neurological complications of the disease, itself. And, despite improvements in subjects' underlying diabetic condition, they appear to have a slightly higher risk of a neurological adverse event on rimonabant.
7.	265	21	1:45 PM	So you can see, individually, the numbers [sic]of events are small. But, in aggregate, they are worrisome especially given the fact that we don't have follow up or imaging studies on many of these patients.
8.	265-266	21	1:45 PM	I am just going to review one of the patient narratives here as it highlights a concern of ours over the accurate characterization of neurological adverse events. This is a case of a 59-year-old female with no relevant medical history who was enrolled in SERENADE.
9.	270	26	1:50 PM	That, in conjunction with the fact that rimonabant accumulates two-fold in the brain with multiple dosing, so AUC:Cmax ratios probably overestimate safety margins in humans, formed the basis for our concerns regarding the seizure potential in humans.

	Transcript	PPT	1	_
	Page (1)	Slide (2)	(3)	Quote (4)
10.	272	30/31	1:53 PM	In ongoing studies, where randomization is 1 to 1, there have been 8 cases of seizure reported. These include 6 cases on rimonabant 20 and 2 on placebo. The numbers remain small. However, the imbalance between rimonabant and placebo persists. Given the known anticonvulsant properties of endocannabinoids and the preclinical finding with rimonabant, and given the 16 cases of seizure which occurred during the trial despite efforts to exclude high-risk patients, as well as the continued imbalance in the occurrence of seizure in ongoing trials, we remain concerned about rimonabant's potential to increase seizure risk. Additional clinical experience will clarify this potential risk.
11.	277-278	37	1:59 PM	Again, because we don't include events occurring in subjects who were re-randomized during a second randomization to a different treatment arm and because we have confined our analyses to the one adverse-event dataset, this should be viewed as an underestimate. An overriding theme is the almost 2 to 1 imbalance that seems to
12.	279-280	41	2:01 PM	The incidence of a psychiatric adverse event in subjects who had a baseline history of depression was 32.2 versus 17.6 among patients who did not have a baseline history of depression. But keep in mind that subjects with more severe forms of depressed mood disorders were excluded from the trials and also bear in mind that this also indicates that roughly 88 percent of subjects who experienced a psychiatric adverse event did not have a baseline history of depressed mood disorder and disturbances. This is in contrast to what the company has told you that having a baseline history of depressed mood is predictive for who will have difficulties with rimonabant.

	Transcript	PPT		
	Page	Slide	Time ¹	Quote
	(1)	(2)	(3)	(4)
13.	281	42	2:03 PM	Here you see that 8.5 percent of rimonabant subjects who were enrolledand this is the whole group8.5 percent of people who were enrolled in the RIO studies on rimonabant 20 mg required the institution of an anxiolytic or hypnotic during the trial versus 4.1 percent of those on placebo.
				Another 4.8 percent of subjects required institution of an anti- depressant versus 2.9 percent of those on placebo. These numbers are felt to be an underestimate because some subjects were placed on a beta-blocker for their anxiety symptoms. Our review of the patient narratives and case-report forms reveals still others whose treatments were simply not recorded in the datasets.
14.	281-282	43	2:04 PM	Our conclusion was that rimonabant 20 mg was associated with an approximate doubling of the risk of a psychiatric adverse event and a roughly three-fold increase in discontinuation from the trials due to these events. These events included predominantly anxiety disorders and symptoms, depressed mood disorders and disturbances and sleep disorders and disturbances. This was from trial data in subjects in whom major psychiatric disorders had been excluded. What remains unknown is what the experience with rimonabant will be in a less highly screened and potentially more depressed patient population.
15.	292-293	60	2:16 PM	So, in summary, our meta-analysis indicates an increased risk for suicidality, specifically suicidal ideation, in subjects taking rimonabant 20 mg versus placebo. There is an increase in relative risk of 80 to 100 percent and an increase in absolute risk of 0.3 percent.
				This correlates with one additional case of suicidality per year for every 300 patients treated. And these estimates may be low, given the higher percentage of rimonabant-treated patients who drop out of the study due to psychiatric adverse events.

	Transcript Page (1)	PPT Slide (2)	Time ¹ (3)	Quote (4)
16.	297-298	64	2:22 PM	The risks associated with the use of rimonabant include an approximate doubling in the risk of psychiatric adverse events specifically depression, anxiety, insomnia, and mood disturbances, an approximate doubling in the risk of suicidality, specifically, suicidal ideation, an increase in a constellation of neurological adverse events of unclear significance, a possible increase in seizure risk, an increase in nausea and vomiting—which we haven't really discussed today although it is the most commonly reported adverse events, and many of these risks appear more pronounced in diabetics—and as yet to be identified risks, and there will be further risks.
17.	298	64	2:23 PM	Our knowledge of the endocannabinoid system is still evolving and there is a lot more to be learned, but keep in mind the signals we are seeing are in a relatively small and highly select population, carefully screened and receiving drug in a controlled setting.
18.	298	64	2:24 PM	The potential market for this drug and our continued uncertainty about its risks, both known and unknown, lead to our concern about the use of this drug in the general population.
19.	298	64	2:24 PM	Weight loss may have benefits in and of itself. However, the effect of drug-associated weight loss on cardiovascular morbidity and mortality remains unproven. The results of studies, such as the Women's Health Initiative, highlight a concern with continued reliance on surrogate endpoints that ultimately do not achieve the desired goal of reducing cardiovascular morbidity and mortality.

Statements by Dr. Amy Egan Expressing Concern about Rimonabant During June 13, 2007 Presentation to the Advisory Committee

	Transcript	PPT		
	Page	Slide	Time ¹	Quote
	(1)	(2)	(3)	(4)
20.	305-306	-	2:32 PM	DR. GILMAN: Under "cognitive disorders," there were many terms Were there any objective measurements made? or an individual on the site recorded?
				DR. EGAN: That's correct. This would have been recorded by he investigator at the investigator site. Now, one of our concerns was, yes, we actuallyif you type up a table with all of the neurologic adverse events that were listed by preferred term, it encompasses 3 pages. So, that is why we said we had a great deal of difficulty getting a grasp on what they all meant, because so many different terms were used. Part of this may have been because that is how the patients were reporting it. It may have been just difference in investigators.
21.	313	-	2:42 PM	We do have a slide prepared on the psychotic and dissociative events that occurred, which you are right, they arewe didn't discuss this, but we are concerned about evidence of psychosis, and you can see the imbalance here where 2.7 percent of rimonabant users versus 0.5 percent of placeboand this is just the RIO study, so we haven't factored in the schizophrenicsexperience a dissociative or psychotic disorder, and we had 1 percent developed.
22.	314	-	2:43 PM	So, yes, you are right. One of the populations we do have tremendous concerns with are the patients on atypical antipsychotics who tend to gain a lot of weight and would likely seek out a drug like this.

Notes and Sources:

DDT

Quotes are from the FDA Advisory Committee Meeting on 6/13/07 at 1:32 p.m. - 3:00 p.m., where Dr. Egan points to potential problems or states a concern the FDA has.

Estimated based on audio tape of the FDA Advisory Committee.

If time goes over to the following minute, the time shown is the beginning time.

Meeting was scheduled to resume after lunch at 1:00 p.m (see draft agenda for AdCom meeting).

We assume, therefore, that the meeting restarted at 1:00 p.m. Sidney Wolfe, first speaker after lunch, started at 3:56 on the transcript video. Assume it took 1 minute to introduce

Mr. Wolfe before the video started up again (estimate per transcript), then 3:56 - 1 minute = 3:55 on the transcript = 1:00 p.m.

Members of the June 13, 2007 FDA Advisory Committee Pointed to a Number of Issues

				Factor Cited in Explaining Non-Favorable Vote Psychiatric			
Speaker ²	Page	Issue	Quote ³	Suicidality	Adverse Events	Others	
(1)	$\frac{1 \text{ age}}{(2)}$	(3)	(4)	(5)	(6)	(7)	
1. Dr. Jules Hirsch	330-335	Weight loss is not sustained	[T]he first problem I have with it is that, when I examined the weight loss curve, I note it seems familiar to me. It is exactly the same sort of weight loss curve that sibutramine gives and orlistat or Zenecal gives. What happens is the weight comes down, the majority of it, about 5 percent more than placebo effect in the first 6 or 8 months, and then it sort of flattens out, but if you look carefully, just before a year or two, the inevitable is happening. The weight is beginning to come back, and that happens with both of those drugs.			X	
		Drug not attacking fundamental cause of obesity	But perhaps what is happening in all of these cases, something else leads to the weight loss rather than a correction of a fundamental aberration that caused the obesity. I feel strongly that we are learning more about these aberrations from the study of the drugs but that none of them is attacking fundamental causes including this one, in my opinion.				
		Doubts about positive effects on comorbidities	I think if one really wanted to know about [the independent effect of the drug], the study that has to be done is that rimonabant has to be given to people specifically for that examination, and maybe that is being done or will be done, and great efforts made to maintain no weight loss, but exactly the same weight in a group of obese individuals, and study what happens with carbohydrate intolerance. Without such a study we may not really know that. So, I am worried about any notion that this drug is better than others because of the good things that it does specifically with these comorbidities.				
		Disappointing amount of weight loss and Small percentage of success in population	The problem with the whole thing, as I see it, is, number one, the number of people who are going to lose weight is fairly small. Apparently, about half of the people who are given the drug will lose some weight, 5 percent or so of their body weight. About a quarter of the group will lose the wanted 10 percent or so but, even in these circumstances, it is not much. Remember that we were presented several times with data that showed that when you tell people you are going to lose 17 percent of your body weight, which was picked because of what some drugs and stuff do for this, that people find that very disappointing. And this group will find it disappointing, too, those who are put on rimonabant.				

Members of the June 13, 2007 FDA Advisory Committee Pointed to a Number of Issues

					Cited in Explained	O
Speaker ²	Page	Issue	Quote ³	Suicidality	Events	Others
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Risk management plan not practical	I worry, however, about the statement that the help of 20,000 physicians will be enlisted [in the risk management plan] If the sponsors really feel that can be done, I am sort of surprised, because it shows some lack of understanding of the sorry current state of our health-care management in this country generally, that such a program could possibly be undertaken without the kinds of duress and so on that would probably be not suitable or legal or whatever in these circumstances. In any event, the idea [risk management plan] is a wonderful one, but I don't think we can do that, or I don't believe that can come about unless I misunderstood it completely.			
2. Dr. Paul Woolf	336-337	Not enough patients studied Disappointing	We have a first in class. We have a whole bunch of studies that are in progress and particularly the stress, as I said before, that it did not appear that the sponsor had the requisite number of patients to meet the target of 1,500. By the way, that number was reconfirmed less than four years ago at a committee meeting that I was participating in that agreed that 1,500 was the bar that needed to be reached for a one-year trial. So, we don't have enough patients on here for a long enough period of time to know what is going to happen down the road, and we have enough concerns. If the drug could cause a 30 percent weight loss, I think we would all be impring up and down and throwing our beta in			X
		amount of weight loss and small percentage of success in population	would all be jumping up and down and throwing our hats in the air and say this is marvelous, and we might be willing to overlook the concerns. But as Dr. Hirsch pointed out, this drug has about the same efficacy as the other two approved drugs.			
3. Dr. Sid Gilman	340-342	Incidence of psychiatric adverse events; high attrition rate	My level of concern regarding rimonabant and psychiatric adverse events is very high. In other words, I am very concerned that, first, there is a high dropout rate for various reasons. Second, there is a high proportion of people who develop suicidal ideation on high dose versus lower dose versus placebo. Therefore, I think this is a drug that needs further understanding with respect to what it does to people's psyche.	X	X	X

Members of the June 13, 2007 FDA Advisory Committee Pointed to a Number of Issues

					Cited in Expla 1-Favorable Vo Psychiatric	
_					Adverse	
Speaker ²	Page	Issue	Quote ³	Suicidality	Events	Others
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Neurological side effects; seizures / epilepsy	With regard to the neurologic problems, I am mostly concerned about epilepsy, less concerned about multiple sclerosis But with the seizure history, the seizure disorders, I went through these tables very carefully actually and I am struck that many of the patients who had a convulsive disorder did have a history of a previous epileptic episode of some sort even though the data we have are very sketchy. There are probably three of those cases that did not have a history of previous epileptic seizure or frontal meningioma or an astrocytoma or some other cause for a seizure disorder. So, it looks as if a previous history of a seizure does constitute a risk factor, at least in this group that were reported. All the same, seizures occurred more frequently in the rimonabant treated group 8 cases than in the placebo group 3 cases. So, I have concern about the neurology with respect to seizure disorders.			
		Adverse events defined too generally Quality of safety data	For the rest, I have already said it is very unclear what these patients were experiencing, what do they mean by dizziness, what memory impairment do they have. I don't think we have adequate information despite the very large number of cases exposed. It's a huge number of cases with grossly inadequate data. What do they mean by memory disturbance? Is there anything objective about that? What do they mean by lethargy? These are words, but they are not documented with anything that one can quantify. So, I am concerned about that. I am concerned about the quality, not the amount of safety data.			
Dr. Robert Kreisberg	343	Inadequate study sample/ population	I am sorry that Dr. Hirsch said most of what I wanted to say, but I will paraphrase it to say that I am concerned about the relatively low frequency of adverse events that occur in the population that has been studied when you consider this might be extrapolated to a much larger group of patients who would be eligible for the drug.		X	X

Members of the June 13, 2007 FDA Advisory Committee Pointed to a Number of Issues

					· Cited in Expla n-Favorable Vo	~
					Psychiatric Adverse	
Speaker ²	Page	Issue	Quote ³	Suicidality	Events	Others
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Number needed to harm and number needed to treat is about the same	Some rough calculations that I have made based upon only the psychiatric and neurological adverse effects, recognizing that some of them might be rather trivial, the absolute increase in risk is such that the number that you need to treat for harm is 6, and the number you need to treat for benefit of a 5 percent weight loss is about 4, and for a 10 percent weight loss is about 6. So it looks to me that the number needed to harm and the number needed to treat are pretty well balanced based upon the information.			
	348-349	Doubts about positive effects on comorbidities	The second thing is that I think the weight loss is modest and it has all of the characteristics that Dr. Hirsch described so elegantly. I, personally, believe that the sponsor's claim that the prespecified regression analysis accurately depicts what the weight-independent effects of the drug are on important metabolic parameters. I actually like Dr. Arrone's more even-handed approach which is simply to say that the use of this drug was associated with reduction in cardiovascular risk without claiming that there was an additional mechanism beyond weight loss. I, personally, believe that you would have to do the study to convince me that there was this weight-independent effect. You might be interested to know that I looked up "deduced" because you use the term "deduced" in the briefing document. In the dictionary, it says, "To reach a conclusion by reasoning, to infer from a general principle." That sort of implies that you don't need data to do it. I think you need hard data to make that claim and I don't think the data that you have is hard.			
5. Dr. Dom Ciraulo	349-350	Incidence of psychiatric events; high attrition rate Anxiety, aggression	From my perspective, I think that the reports of the psychiatric adverse effects are too high and too serious, especially given the attrition. I really think thatyou know, you can argue when you lose so many people from a study that efficacy is affected. You can argue it both ways. People leave because they are not getting better or because they have gotten better. But I think what the real implication here is, you have lost data on adverse effects and I think you have lost serious data on depression and anxiety. The other issue I would like to emphasize is that anxiety is a serious psychiatric disorder. It is not being afraid to talk	X	X	X
			to your boss. It is associated with suicide and it is not to be made light of. I think that we are somewhat underestimating that.			

Members of the June 13, 2007 FDA Advisory Committee Pointed to a Number of Issues

					Cited in Explain- -Favorable V	~
					Psychiatric Adverse	
Speaker ²	Page	Issue	Quote ³	Suicidality	Events	Others
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			Then I think the other is the slide that was shown on aggression and the possibility that some of this anxiety may be more of a psychotic aggression nature. And I think that is a very, very serious problem. I also think that the point that was made that subjects who have a baseline history of depression may be at higher risk but people who don't have a history of depression in the past are also at risk. I am also not clear about treatment. I really don't know what happens when these people get depressed or get anxious. I understand that some of them get			
		Neurological side	treated, but I worry about follow up, how good the follow up is, and what the consequences are. So, as far asthe only thing I want to say about neurological			
		effects; seizures / epilepsy	side effects, which is not my area, I think that some of them may seem minor. Dizziness may seem minor. Balance may seem minor. But somebody falls and breaks a hip. Somebody is in a car and has a seizure. That person is affected and society is affected. So I would not minimize the neurological consquences that have been reported. So, essentially, I vote as the others.			
6. Ms. Malanie Coffin	352	Incidence of psychiatric adverse events including anxiety and aggression	But I have to be very honest. As I was reading through the prep documents, my eyes got really big on quite a few issues. I think it is interesting that it has been a couple of times said that serious adverse events required hospitalization. But I would agree that a jump in anxiety is pretty serious to the individual that is actually having that.	X	X	X
			I am concerned about the extrapolation of both the aggression in the males, or the suicides in the males, as Bob talked about and also the child-bearing. I think it is great, actually, that the sponsor did not intend to direct market for one year out of the shoot. But I will go back to what Lynn said and what I have experienced is that patientspeople who are overweight and obese are erate, desperate, desperate, for any measure.			
			So I think that safety datait still makes me very uncomfortable. And so I would go with the rest of the panel on Question 2 that I would like to see a little bit more.			
7. Dr. Phil Wang	354-355	Incidence of psychiatric adverse events	I think, although we still have some questions about the data we have seen, it appears there is an important safety signal emerging with significant associations between the agent and depression and suicidality.	X	X	X

Members of the June 13, 2007 FDA Advisory Committee Pointed to a Number of Issues

Regarding Their Vote Not to Recommend Rimonabant for Approval¹

Factor Cited in Explaining

				No	n-Favorable Vo	ote
					Psychiatric Adverse	
Speaker ²	Page	Issue	Quote ³	Suicidality	Events	Others
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			Unfortunately, the data you showed indicate that the doubling of risk is still present in even the subgroup that doesn't have a history of psychiatric illness.			
		Need for additional data / studies	So I think there is a need to then continue to pursue further other subgroup analyses that maybe might indicate a subpopulation in whom the cost/benefit, risk/benefit, analysis is favorable. In the data that were raised, the reason why I was asking those questions earlier, I think there is one potential candidate group and that is the folks with higher BMIs, the extreme obesity folks. It looks like there is some preferential efficacy in them. To my back-of-the-envelope calculation, it looks like you actually have lower risks of these adverse psychiatric events in thatmaybe a group, you know, with, I don't know, BMIs greater than 40 or something. But this is all going to take more data, I think, and more subgroup analyses to sort of explore this route. So I think I would vote that more data is necessary before proceeding.			
8. Dr. Wayne Goodman	356-358	Incidence of psychiatric adverse events; High attrition rate; need for additional data / studies	I think that these psychiatric side effects are prevalent. Some of them are quite significant. Some of them represent hard endpoints whereas the others are softer endpoints. There is the risk that others have mentioned that there will be some proliferation, some generalization, to other populations where the risk may be higher. One area where I would like to seeI wish we had some additional datais the fate of those patients who wind up being terminated from the trial or the treatment because of development of depression. I would like to know more about their long-term fate in terms of how long they need to be on anti-depressants or whether there is actually a possibility in the future of considering the combined use of rimonabant and an anti-depressant. I understand why it was excluded from		X	X
			the trials. I would say that I would like to see additional safety data.			

Members of the June 13, 2007 FDA Advisory Committee Pointed to a Number of Issues

Regarding Their Vote Not to Recommend Rimonabant for Approval¹

Factor Cited in Explaining

					n-Favorable V Psychiatric Adverse	~
Speaker ²	Page	Issue	Quote ³	Suicidality	Events	Others
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Quality of life in terms of Drug's risk/benefit	It is hard for me, too, to try to think about my concern about a risk in the absence of the consideration of the benefit. I go back to the earlier questions I had about the quality-of-life data.			
			That, perhaps, troubles me more than anything else is that, when I try to reconcilesay, on one hand, well, it is clear that there is an efficacy signal. The patients are going to be enjoying some decrease in weight that has benefits, medical benefits, as well as some quality-of-life improvement.			
			On the other hand, it is offset by a diminished quality of life in other areas including the emotional and mental life functioning. I understand that that may represent this disproportion of contribution of those patients who had the most adverse psychiatric events. Yet we are still left with looking at what the mean changes are. And they are pretty glaring in terms of the association between improvement and physical well being and emotional well being overall. So that probably gives me the most caution.			
Dr. Clifford Rosen, Chairman ⁴	358-359	Underestimation of the impairment of quality of life	I just wanted to ask you [Dr. Goodman] a particular question. You seem to have focused on that quality-of-life issue that was presented in the slides by the sponsor. It seems to me that some of these were carryovers from their last visit before they dropped out. So we may be even underestimating the impairment in quality of life because we are missing a whole group of people.			
9. Dr. Michael Proschan	359-361	High attrition rate; high proportion of suicidal ideation on higher dose vs. placebo	I think it is clear that there is a benefit of this drug. I am not sure that it is entirewell, I worry about the high dropout rate and I am not sure which way the bias goes when you use last observation carried forward. I mean, you would think, in certain ways, that that should make it look even worse for the drug because you would think that people who dropped out in the placebo arm may have been gaining weight and, if it continued, they would have gained even more weight. On the other hand, they may have dropped out at a random high because, I am gaining weight, whereas, maybe if they had continued, they would have gotten over the hump, so to speak. So it is hard to say which way that will go. But I think it is pretty clear that, even with that high dropout, there is some benefit of the drug on weight loss.	X	X	X

Members of the June 13, 2007 FDA Advisory Committee Pointed to a Number of Issues

					Cited in Expl n-Favorable V	
					Psychiatric Adverse	
Speaker ²	Page	Issue	Quote ³	Suicidality	Events	Others
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Incidence of psychiatric adverse events	Anyway, the AEs, I have a high level of concern about all of them. I think, even if you look at the company's own tables, I think it is pretty clear that, for example, suicidal ideation is greater. I think neurological symptoms, depression, anxiety; these are biologically plausible.			
			I do appreciate the fact that ascertainment bias could be partially responsible. I don't think it explains it all. And no long-term data. I worry about what is going to happen when a patient is on this drug for a longer amount of time. I also worry about the fact that heavier people, although they are apparently getting more benefit in terms of weight loss, the half-life of the drug is longer and so, presumably, they might get more of the adverse consequences.			
10. Dr. Katherine Flegal	362-364	Incidence of psychiatric adverse events	I think this drug could be of benefit to many people but I am also concerned, as everybody else is, about theI think the data on safety are not definitive but are very worrisome and seem to have some degree of biological plausibility. There is the high dropout rate which may minimize the number of adverse events that were actually reported.		X	X
		Number needed to harm and number needed to treat is about the same	So I think there is a large pool of people who may not really realize the benefits of the drug but could only realize possible adverse events and that would include a lot of people who have BMIs below 27, many of whom are probably going to be women because, down to a BMI of about 21, about half of women consider themselves overweight and would like to weigh less.			
11. Dr. Jessica Henderson	364-365	Inadequate study sample/ population; need for additional data / studies	I have very high concern about the safety data. When you look at the lifetime exposure in the animal studies, it is very clear that we need more long-term data in humans and especially, like has already been said, we are going to have massive use of this drug and we just have a very small group of people for a two-year study. But yet this is presented as a drug that is going to be lifetime because it is a chronic—obesity is a chronic disease; therefore this will be long-term use. But we don't have long-term data. I don't consider two years long-term data. I would at least want to come back to this after the CRESCENDO study comes back and at least have some five-year dataSo that is my primary concern is the long-term data.			X

Members of the June 13, 2007 FDA Advisory Committee Pointed to a Number of Issues

Regarding Their Vote Not to Recommend Rimonabant for Approval¹

					Cited in Expl 1-Favorable V	O
					Psychiatric Adverse	
Speaker ²	Page	Issue	Quote ³	Suicidality	Events	Others
(1)	(2)	(3)	(4)	(5)	(6)	(7)
12. Dr. Tom Carpenter	366	Incidence of psychiatric adverse events; high attrition rate; seizures	It is not a system that is directed specifically to appetite alone. Hence, I think the side-effect profile that we see reflects that. I think that there is very significant concern about particularly the depression and suicidality issues. I am a little bit less concerned but may have to do with the limited numbers in terms ofand definitionsrelated to the seizure data. But I think, also, when one looks overall at the CNS data together in whichever analysis you see, there is considerable concern. Moreover, we may be underestimating that, in part, because of the high attrition rate of the study	X	X	X
13. Dr. Ken Burman	367-368	Divergent data between Sanofi and FDA	I agree with most of the comments that were mentioned earlier. I do want to emphasize the dilemma of trying to balance the pros and cons of this medication and also emphasize the divergent conclusions that are apparent to me from the sponsor and from the FDA.			X
		Reproduction, hypertension	I am concerned specifically about the longer-term effect over several years of this agent not only with the neurological symptoms just noted but also with other things such as reproduction and hypertension.			
		Inadequate study sample/ population	I am concerned that the studies were done in mainly caucasians and may or may not apply, as was implied, to other ethnic groups. I am concerned about the ability of previous psychiatric disease as a screening method to predict whether somebody who is put on rimonabant will develop further psychiatric disease, and there obviously was a discrepancy between the two presentations.			
14. Dr. Clifford Rosen, Chairman ⁵	371	Incidence of psychiatric adverse events; need for additional data / studies	I think that is actually exciting, that you can get weight loss through this system. But what I am really troubled by is the lack of good safety data. Now, in clinical research, and I have done it for a living for 20 years, AEs are not a big deal usually. They are recorded by the monitor or the nurse or whoever is in the clinic or the physician, and then they are checked off. But, in this particular case, the adverse events, not the serious adverse events, but the adverse events tell the story. And we don't have enough information. I think that, in retrospect, when we look at the system that we are acting on with this agent, we need that information.		X	X

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Members of the June 13, 2007 FDA Advisory Committee Pointed to a Number of Issues

Regarding Their Vote Not to Recommend Rimonabant for Approval¹

				Factor	· Cited in Expla	aining
				No	ote	
					Psychiatric	
Speaker ²	Page	Issue	Quote ³	Suicidality	Events	Others
(1)	(2)	(3)	(4)	(5)	(6)	(7)

Notes and Sources:

Speakers are members of the FDA Advisory Committee.

Data are from part 4 of the FDA Advisory Committee Meeting on June 13, 2007 available at

http://www.fda.gov/ohrms/dockets/ac/07/transcripts/2007-4306t1-Part4.pdf

- ¹ Advisory Committee Meeting members provided responses to three questions:
- Q1: Please discuss your level of concern regarding rimonabant and psychiatric adverse events, in particular depression and suicidality, and neurological adverse events, in particular seizures, and the reasons behind your thinking on these issues.
- Q2a: Do you believe that the currently available data sufficiently characterize rimonabant's safety profile (vote requested)?
- Q2b: If no, please discuss what additional data should be obtained.
- Q3a: Based on the currently available data, do you believe rimonabant has a favorable risk-benefit profile and should be approved for the indication of weight management in individuals with a body mass index of > 30 kg/m2 and > 27 kg/m2 when accompanied by at least one comorbid condition (vote requested)? Q3b: If no, please explain why and discuss what additional information the sponsor could obtain that might improve rimonabant's risk-benefit profile.
- These questions are in the FDA's "Summary Minutes of the Endocrinologic and Metabolic Drugs Advisory Committee meeting on June 13, 2007" document available at http://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4306m1-final.pdf.
- ² The Advisory Committee discusses questions 1 and 2 at the same time. The exhibit is ordered chronologically by the order in which the speakers discuss and vote on these questions, unless otherwise noted.
- ³ Quotes are from the Advisory Committee's discussion of question 1 and vote on question 2 only. After the vote on question 2, because Dr. Rosen (Advisory Committee chairman) thought sufficient comments were provided regarding questions 3 during the discussion of question 2, there is only brief discussion on question 3 prior to the vote on that question. Quotes from this section are not included.
- ⁴ Comment in response to Dr. Goodman's statement. Dr. Rosen's discussion and vote are later in the meeting.
- ⁵ Coding for columns (4), (5), and (6) is based on all of Dr. Rosen's comments. See pages 358-359 and 371 in the transcript.

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Exhibit 6 Sanofi-Aventis

Statistical Models of Daily Natural Log (LN) Return to Sanofi-Aventis ADSs

February 24, 2006 through June 8, 2007¹ (N=322)

	Model 1	Model 2 Model 3		Model 4	Model 5 Model 6 Model 7 Model 8	Model 6	Model 7	Model 8	Model 9	Model 10	Model 9 Model 10 Model 11 Model 12	Model 12	Model 13
	(E)	(5)	(3)	4	(<u>3</u>)	9)	6	8	6)	(10)	(11)	(12)	(13)
Constant	-0.0004	-0.0003	-0.0003	-0.0004	-0.0001	-0.0002	-0.0002	-0.0001	0.0002	-0.0003	-0.0003	-0.0003	-0.0002
	-0.57	-0.41	-0.46	-0.58	-0.10	-0.29	-0.24	-0.14	0.34	-0.58	-0.52	-0.50	-0.39
Market Indices ²													
US Stocks NYSE Composite Index Excl. SNY	0.9724 11.43										0.4538 3.55		
S&P 500 Index		0.9935 10.24											0.2811 $I.92$
ADSs NYSE ARCA International Market Index Excl. SNY			0.7540 11.28									0.3722	
S&P ADR Index				0.7919 12.07						0.4452 4.91			
Industry Indices ²													
NYSE ARCA Pharmaceutical Index Excl. SNY					0.9933 10.93								
NYSE Healthcare Index Excl. SNY						1.2110 <i>12.30</i>				0.7279	0.7978	0.8098 5.91	0.9771
S&P 500 Pharmaceuticals Sub Industry Index GICS Level 4							0.8961						
S&P 500 Health Care Sector Index GICS Level 1								1.0187 10.06					
NASDAQ Health Care Index³									0.7202 9.69				
R-Squared Adjusted R-Squared Std. Error	29.01% 28.79% 0.0111	24.67% 24.43% 0.0114	28.47% 28.24% 0.0111	31.29% 31.07% 0.0109	27.20% 26.97% 0.0112	32.12% 31.91% 0.0108	22.20% 21.96% 0.0116	24.04% 23.80% 0.0115	22.70% 22.46% 0.0116	36.90% 36.50% 0.0105	34.70% 34.29% 0.0107	35.53% 35.13% 0.0106	32.90% 32.47% 0.0108

Exhibit 6 Sanofi-Aventis

Ebruary 24, 2006 through June 8, 2007^1 (N=322)

Statistical Models of Daily Natural Log (LN) Return to Sanofi-Aventis ADSs

Data are from Bloomberg Finance L.P.; t-statistics are in italics.

Notes and Sources:

The constant is the expected value of the dependent variable if the independent variable equals zero.

Independent variable

The non-italicized number is the coefficient. It measures change in the dependent variable associated with a one unit change in the independent variable.

The italicized number is the t-statistic. It must exceed 1.97 in absolute value for the relationship between the independent variable and the dependent variable to be statistically significant

at the 5% level.

R-Squared is the percent of variance in the dependent variable that is explained by the independent variable.

The return on October 31, 2006 is excluded from the regressions because that was a day when an alleged misrepresentation entered the market. February 25, 2006 is the day of the first return explained by the independent variable(s).

² Components of each index during the regression period are available from Bloomberg, unless otherwise footnoted. Sanofi is a member of all indices during the regression period, other

For indices that include Sanofi, except S&P ADR Index, weights are available from Bloomberg. For these indices, index returns are stripped of the returns to Sanofi using beginning of than the S&P 500 Index, the S&P 500 Pharmaceuticals Sub Industry Index GICS Level 4, and the S&P 500 Health Care Sector Index GICS Level 1. the month weights, measured at 2 month intervals.

³ Components of the NASDAQ Health Care Index are not available via Bloomberg. We therefore do not know whether Sanofi is among them

Exhibit 7 Sanofi-Aventis <u>Statistical Models of Daily Natural Log (LN) Return to Sanofi Ordinary Shares</u> February 24, 2006 through June 8, 2007¹

	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6	Model 7
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Constant	(0.0005) (0.85)	(0.0004) (0.79)	(0.0005) (0.96)	(0.0001) (0.18)	(0.0005) (0.91)	(0.0005) (0.78)	(0.0003) (0.58)
Market Indices							
CAC 40 Index Excl. SAN ²	0.6667 11.21						
FTSE Eurotop 100 Index Excl. SAN ²		0.8179 12.14					0.5294 6.04
Euronext 100 Index Excl. SAN ²			0.7316 11.32				
Industry Indices							
Bloomberg Europe 500 Pharmaceuticals Index Excl. SAN^2				0.8927 11.45			0.4892 4.91
Bloomberg World Pharmaceuticals Index Excl. SAN^2					0.9367 10.52		
NYSE Healthcare Index Excl. SNY ³						0.9319 9.75	
Estimation Statistics							
R-Squared Adjusted R-Squared Standard Error # of Observations (N)	28.00% 27.78% 0.0101 325	31.32% 31.11% 0.0098 325	28.41% 28.19% 0.0101 325	28.87% 28.65% 0.0100 325	25.53% 25.30% 0.0103 325	23.19% 22.95% 0.0105 317	36.10% 35.70% 0.0095 325

Notes and Sources:

Data are obtained from Bloomberg L.P.

The constant is the expected value of the dependent variable if the independent variable equals zero.

Independent variables

The non-italicized number is the coefficient. It measures change in the dependant variable associated with a one unit change in the independent variable.

The *italicized* number is the t-statistic. It must exceed 1.97 in absolute value for the relationship between the independent variable and the dependent variable to be statistically significant at the 5% level.

R-Squared is the percent of variance in the dependent variable that is explained by the independent variable.

¹ The return on October 31, 2006 is excluded from the regressions because that was a day when an alleged misrepresentation entered the market.

Index returns are stripped of the returns to SAN using beginning of the month weights. SAN weights range from 5.8% to 9.8% in the CAC 40 Index, 1.2% to 1.8% in the FTSE Eurotop 100 Index, 3.4% to 5.6% in the Euronext 100 Index, 14.7% to 21.6% in the Bloomberg Europe 500 Pharmaceuticals Index, and 6.3% to 8.8% in the Bloomberg World Pharmaceuticals Index.

³ Index returns are stripped of the returns to SNY using beginning of the month weights. SNY weights range from 4.2% to 5.4%.

Exhibit 8.a Sanofi-Aventis

Abnormal ADS Price Change Following the February 24, 2006 1:23 a.m. ET Announcement of Financial Results:

4Q05 Adjusted Net Profit of €1.44B Slightly Above Analyst Expectations of €1.43B, Operating Profit of €2.06B Below Consensus of €2.18B, and Guidance for Growth in FY06 EPS of Around 10%, Lower than FY05 Growth of 25.7%; and

"In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency" Regarding Rimonabant¹ 9:00 a.m. ET Earnings Conference Call During which Defendant Le Fur States:

			Cumulative Abnormal	ADS Price Change	Percent	(13)	(12)/first(1)		1.3%	1.4%	0.8%	0.8%	%8.0	
			Cumulative	ADS Pric	Dollar ⁶	(12)			\$0.57	\$0.58	\$0.34	\$0.36	\$0.33	
			t-statistic for Abnormal	ADS Return	Cumulative ⁵	(11)			1.24	68.0	0.43	0.38	0.31	
			t-statistic	ADS	Daily ⁴	(10)			1.24	0.02	(0.52)	0.02	(0.06)	
			Abnormal ADS Price	Return	Daily Cumulative	6)	(8)+prev (9)		0.0131	0.0133	0.0079	0.0081	0.0074	
			Abnorma	Ret	Daily	8)	(2) - (6)		0.0131	0.0002	(0.0055)	0.0002	(0.0006)	
			Predicted ADS	Return	Cumulative	6	(6) + prev(7)		(0.0008)	0.0057	(0.0093)	(0.0034)	(0.0053)	
			Predic	Re	Daily ³	9)			(0.0008)	0.0064	(0.0150)	0.0059	(0.0019)	
NYSE	Healthcare	Index	Return	Excl.	SNY	(5)			(0.0015)	0.0068	(0.0140)	0.0038	(0.0014)	
	NYSE ARCA	International	Market Index	Return	Excl. SNY	(4)			0.0020	0.0033	(0.0088)	0.0082	(0.0014)	
						(2) (3)	(2) + prev(3)		0.0123	0.0190	(0.0014)	0.0047	0.0021	
				Actual ADS LN Return	Daily	(2)	$\ln[(1)/\text{prev}(1)]$ (2) + prev(3)		0.0123	0.0067	(0.0204)	0.0061	(0.0026)	
			ADS	Closing	Price ²	(1)		\$42.69	\$43.22	\$43.51	\$42.63	\$42.89	\$42.78	
					Date			2/23/06	2/24/06	2/27/06	2/28/06	3/1/06	3/2/06	

Notes and Sources:

¹ "Sanofi-Aventis 4Q Net Pft EUR456M Vs EUR1.195B," Dow Jones International News, 2/24/06 1:23 a.m. ET; "Sanofi-Aventis reports 26.0-percent profits injection," Agence France Presse, 2/24/06 4:58 a.m. ET; "Sanofi-aventis Reports Strong Growth of 25.7% in 2005 Adjusted EPS(1); Nearly 90% of synergies delivered by end 2005; Dividend increased by 26.7%," PR Newswire (U.S.), 2/24/06 7:30 a.m. ET; "Q4 2005 Sanofi-Aventis earnings Conference Call- Final," Voxant FD Wire, 2/24/06; "UPDATE 4-Sanofi Q4 net up 21 pct, sees H2 Acomplia launch," Reuters News, 2/24/06 1:48 a.m. ET.

² Data are obtained from Bloomberg, L.P.

NYSE Healthcare Index Excluding SNY. The regression is estimated over the period from February 24, 2006 through June 8, 2007. The estimation period begins with the first day's closing price, not its return. ³ Returns are predicted from a market model that estimates the relationship between the daily returns to Sanofi ADS and the daily returns to the NYSE ARCA International Market Index Excluding SNY and See Exhibit 6.

Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level. The t-statistic must be equal to or exceed 1.97 or 1.65 in absolute value for the abnormal return to be ⁴ Significance is based on the excess return's t-statistic, calculated as the daily excess return divided by the standard error of the regression over the estimation period. statistically significant at the 5% or 10% level, respectively.

⁵ Cumulative excess return t-statistics are calculated as the cumulative excess return divided by the standard error of the regression over the sample period times the square root of the number of days cumulated. Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level.

⁶ Calculated using the formula: \$42.69 * [exp{ (9) + (Days/2) * s^2 } - 1], where s represents the standard error of the regression.

Exhibit 8.b

Abnormal ADS Price Change Following the October 31, 2006 1:00 a.m. ET Announcement¹ of Financial Results: Sanofi-Aventis

3006 Net Profit of £1.7B Above Consensus of £1.52², Sales of £6.9B Below Consensus of £7.35B² Euros as a Result of £0.5ing Plavix Sales to Generic Competition, and Slightly Raised FY06 EPS Growth Outlook from 2%, or £4.83, to "At Least 2%," Below Consensus of £4.96³; and

2:00 a.m. ET Earnings Conference Call During which Defendant Spek States, "It is Easier for Me to Say That We Have Not Submitted New Data in this Respect" Regarding the Approvable Letter for Rimonabant, and that Sanofi "Submitted October 26 a Complete Response to This Approvable Letter....

|Sanofi| Will Not Speculate at All What the FDA Now Has To Do or Will Do and Within Which Timeline"

	,,,	, ,	Cumulative Abnormal	ADS Price Change	Percent	(13)	(12)/first(1)		-1.6%	-1.7%	-3.1%	-3.2%	-3.4%
			Cumulativ	ADS Pri	Dollar ⁶	(12)			(\$0.70)	(\$0.76)	(\$1.34)	(\$1.39)	(\$1.49)
			t-statistic for Abnormal	ADS Return	Cumulative ⁵	(11)			(1.54)	(1.18)	(1.71) *	(1.55)	(1.48)
			t-statistic	ADS	Daily ⁴	(10)			(1.54)	(0.13)	(1.29)	(0.13)	(0.22)
			Abnormal ADS Price	Return	Cumulative	(6)	(8)+prev (9)		(0.0163)	(0.0177)	(0.0314)	(0.0328)	(0.0351)
			Abnorma	Ret	Daily	(8)	(2) - (6)		(0.0163)	(0.0014)	(0.0136)	(0.0014)	(0.0023)
			Predicted ADS	urn	Cumulative	(7)	(6) + prev(7)		(0.0025)	(0.0072)	(0.0013)	(0.0052)	0.0095
			Predict	Return	Daily ³	(9)			(0.0025)	(0.0047)	0.0058	(0.0038)	0.0146
NYSE	Healthcare	Index	Return	Excl.	SNY	(5)			(0.0044)	(0.0044)	0.0063	(0.0048)	0.0112
	NYSE ARCA	International	Market Index	Return	Excl. SNY	4			0.0037	(0.0022)	0.0027	0.0008	0.0158
				Actual ADS LN Return	Cumulative	(2) (3)	(2) + prev(3)		(0.0188)	(0.0249)	(0.0327)	(0.0380)	(0.0256)
				Actual ADS	Daily	(2)	$\ln[(1)/\text{prev}(1)]$ (2) + prev(3)		(0.0188)	(0.0061)	(0.0078)	(0.0052)	0.0123
			ADS	Closing	Price ²	(I)		\$43.50	\$42.69	\$42.43	\$42.10	\$41.88	\$42.40
					Date			10/30/06	10/31/06	11/1/06	11/2/06	11/3/06	11/6/06

¹ "Sanofi-Aventis 3QNet Profit EUR1.7B Vs EUR1.92B," Dow Jones International News, 10/31/06 1:00 a.m. ET; "sanofi-aventis Reiterates FY 2006 EPS Outlook," Reuters Significant Developments, 10/31/06

² There were multiple consensus figures cited in news. The one quoted in the title above is the estimate which is furthest off from the actual. Two other sources reported consensus of £1.57B in profit and €7.28B in sales (see "Generics lower Sanofi's profits," Handelsblatt Wirtschafts- und Finanzzeitung, 10/31/2006 and "UPDATE 4-Sanofi Q3 profit falls on Plavix, health cuts," Reuters News, 10/31/06 1:48 a.m. ETD. In addition, AFP reported consensus of €1.4-1.7B for profit citing a survey by AFX News (see "Sanofi profits fall as heart drug hit by competition in US," Agence France Presse, 10/31/2006 3:06 a.m. ET).

FY06 EPS Guidance of e4.83 is calculated applying 2% growth to reported FY05 adjusted EPS of e4.74. The consensus of e4.96 implies EPS growth of around 4.6%. "Sanofi-aventis Reports Strong A different Dow Jones article reported consensus of €7.25B in sales ("UPDATE: Sanofi-Aventis Profit Falls 12% On Copycat Drugs," Dow Jones Business News, 10/31/06 4:31 a.m. ET).

"Q3 2006 Sanofi-Aventis Earnings Conference Call- Final," Voxamt FD Wire, 10/31/06; "Sanoff-aventis Announces Third Quarter Sales and Earnings for 2006: Sales Growth of 2.6% on a Comparable Growth of 25.7% in 2005 Adjusted EPS(1); Nearly 90% of synergies delivered by end 2005; Dividend increased by 26.7%," PR Newswire (U.S.), 2/24/06 7:30 a.m. ET) Basis(1); Adjusted EPS Growth of 15.0%, or 7.5% Excluding Selected Items(3)," PR Newswire (U.S.), 10/31/06 9:31 a.m. ET.

cumulated. Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level.

Data are obtained from Bloomberg, L.P.

NYSE Healthcare Index Excluding SNY. The regression is estimated over the period from February 24, 2006 through June 8, 2007. The estimation period begins with the first day's closing price, not its return. See Exhibit 6. Esturns are predicted from a market model that estimates the relationship between the daily returns to Sanofi ADS and the daily returns to the NYSE ARCA International Market Index Excluding SNY and

Significance is based on the excess return's t-statistic, calculated as the daily excess return divided by the standard error of the regression over the estimation period. Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level. The t-statistic must be equal to or exceed 1.97 or 1.65 in absolute value for the abnormal return to be statistically significant at the 5% or 10% level, respectively. Cumulative excess return t-statistics are calculated as the cumulative excess return divided by the standard error of the regression over the sample period times the square root of the number of days

Calculated using the formula: \$43.50 * [exp{ (9) + (Days/2) * s^2 } - 1], where s represents the standard error of the regression.

Exhibit 8.c Sanofi-Aventis

Posting of Briefing Documents on FDA Website, Stating that Rimonabant Is "Associated with Statistically and Clinically Significant Weight Loss" and That the FDA is Concerned About an Increase in Psychiatric Side Effects, in Particular the Statistically Significant Increase in Suicidality Abnormal ADS Price Change Following the June 11, 2007 10:12 a.m. ET

			Abnormal	Change	Percent	(13)	(12)/first(1)		%6.0-	-1.4%	-5.4%	%9.6-	-9.5%	
			Cumulative Abnormal	ADS Price Change	Dollar ⁶	(12)			(\$0.43)	(\$0.63)	(\$2.46)	(\$4.38)	(\$4.34)	
			Abnormal	turn	Cumulative ⁵	(11)			(0.89)	(0.94)	(3.04) **	(4.79) **	(4.24) **	
			t-statistic for Abnormal	ADS Return	Daily ⁴	(10)			(0.89)	(0.43)	(3.94) **	(4.32) **	60.0	
			Abnormal ADS Price	ırn	Cumulative	6)	(8)+prev (9)		(0.0095)	(0.0140)	(0.0557)	(0.1015)	(0.1005)	
			Abnormal	Return	Daily	(8)	(2) - (6)		(0.0095)	(0.0046)	(0.0417)	(0.0457)	0.0010	
			d ADS	ırn	Cumulative	6	(6) + prev(7)		0.0015	(0.0109)	0.0009	0.0053	0.0161	
			Predicted ADS	Return	Daily ³	9)			0.0015	(0.0124)	0.0117	0.0045	0.0108	
NYSE	Healthcare	Index	Return	Excl.	SNY	(5)			0.0017	(0.0089)	0.0079	0.0012	0.0081	
	NYSE ARCA	International	Market Index	Return	Excl. SNY	(4)			0.0012	(0.0132)	0.0151	0.0102	0.0121	
				ı		(3)	(2) + prev(3)		(0.0079)	(0.0249)	(0.0549)	(0.0961)	(0.0843)	
				Actual ADS LN Return	Daily		ln[(1)/prev(1)] (2) + prev(3)		(0.0079)	(0.0170)	(0.0300)	(0.0412)	0.0118	
			ADS	Closing	Price ²	Ξ		\$45.50	\$45.14	\$44.38	\$43.07	\$41.33	\$41.82	
					Date			20/8/9	6/11/07	6/12/07	6/13/07	6/14/07	6/15/07	

Notes and Sources:

¹ "FDA: Sanofi Weight-Loss Drug Increases Sociality," Dow Jones News Service, 6/11/07 10:12 a.m. ET.

² Data are obtained from Bloomberg, L.P.

NYSE Healthcare Index Excluding SNY. The regression is estimated over the period from February 24, 2006 through June 8, 2007. The estimation period begins with the first day's closing price, not its return. ³ Returns are predicted from a market model that estimates the relationship between the daily returns to Sanofi ADS and the daily returns to the NYSE ARCA International Market Index Excluding SNY and See Exhibit 6.

Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level. The t-statistic must be equal to or exceed 1.97 or 1.65 in absolute value for the abnormal return to be 4 Significance is based on the excess return's t-statistic, calculated as the daily excess return divided by the standard error of the regression over the estimation period. statistically significant at the 5% or 10% level, respectively.

⁵ Cumulative excess return t-statistics are calculated as the cumulative excess return divided by the standard error of the regression over the sample period times the square root of the number of days cumulated. Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level.

⁶ Calculated using the formula: \$45.50 * [exp{(9) + (Days/2) * s^2} - 1], where s represents the standard error of the regression.

Exhibit 8.d Sanofi-Aventis

Abnormal ADS Price Change Following the June 13, 2007 8:00 a.m. to 4:00 p.m. ET Public Meeting of an FDA Advisory Committee and

4:08 p.m. ET unaimous "No" Vote by the FDA Advisory Committee to the Questions:

Weight Management in Individuals with a BMI of Greater or Equal to 30 and Greater than 27 when Accompanied by at Lease One Comorbid Condition?" "Based on the Current Data, Do You that Believe Rimonabant Has a Favorable Risk/Benefit Profile and Should be Approved for the Indication of

ļ					NYSE								
International Index Inde				NYSE ARCA	Healthcare								
Market Index Return Fredicted ADS Abnormal ADS Price Frestrin ADS Return Cumulative Abnormal Cumulative Abnormal ADS Price Change Above Abov				International	Index								
Return Excl. SNY Daily³ Cumulative Daily³ Daily³ Cumulative Daily³ Daily³ Cumulative Daily³ Cumulative Daily³ Perc (13) (4) (5) (6) (7) (8) (7) (8) (10) (11) (12) (13) (4) (5) (6) (7) (8) (2) - (6) (8) + prev (9) (11) (12) (12) (12) (12)/fin (6) (6) (7) (8) (8) + prev (9) (10) (11) (12) (12)/fin (12				Market Index	Return	Predic	cted ADS	Abnorm	al ADS Price	t-statistic fo	r Abnormal	Cumulativ	e Abnormal
Excl. SNY SNY Daily³ Cumulative Daily³ Cumulative Cumulative Dollar° Pere (13) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (6) (7) (8) (7) (8) (11) (11) (12) (12) (13) (6) (7) (8) (7) (8) (8) (8) (12) (Actual ADS	S LN Return	Return	Excl.	Re	eturn	Re	turn	ADS	Return	ADS Pric	e Change
(4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (6) + prev(7) (6) + prev(7) (2) - (6) (8) + prev(9) (11) (12) / fit (6) + prev(7) (6) + prev(7) (2) - (6) (8) + prev(9) (11) (12) / fit (10) 0.0151 (0.0079 (0.0117 (0.0417) (0.0417) (3.94) ** (3.94) ** (3.181) (0.0102 (0.0045 (0.0162 (0.0457) (0.0874) (4.32) ** (5.84) ** (3.34) ** (3.367) (0.0012 (0.0037) (0.0030) (0.0240) (0.0083) (0.0947) (0.78) (4.47) ** (\$4.00) (0.0035 (0.0012 (0.0020) (0.0020) (0.0038) (0.0999) (0.36 (3.84) ** (\$3.84)		1	Cumulative		SNY	Daily ³	Cumulative	Daily	Cumulative	Daily ⁴	Cumulative ⁵	Dollar ⁶	Percent
(0.0151 0.0079 0.0117 (0.0417) (0.0			(3)		(5)	(9)	6)	8)	6)	(10)	(11)	(12)	(13)
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	_	[(1)/prev(1)]	(2) + prev(3)				(6) + prev(7)	(2) - (6)	(8)+prev (9)				(12)/first(1)
(0.0300) 0.0151 0.0079 0.0117 0.0117 (0.0417) (0.0417) (0.0417) (0.0418) ** (3.94) ** (\$1.81) (0.0712) 0.0102 0.0045 0.0162 (0.0457) (0.0874) (4.32) ** (5.84) ** (\$1.81) (0.0594) 0.0121 0.0081 0.0108 0.0270 0.0010 (0.0864) 0.09 (4.71) ** (\$3.67) (0.0707) 0.0006 (0.0037) (0.0030) 0.0240 (0.0038) (0.0947) (0.78) (4.47) ** (\$4.47) ** (0.0649) 0.0035 0.0012 0.0020 0.0260 0.0038 (0.0999) 0.36 (3.84) ** (\$3.84) **													
(0.0712) 0.0102 0.0012 0.0045 0.0162 (0.0457) (0.0844) (4.32) ** (5.84) ** (5.84) ** (5.371) (3.377) (0.0594) 0.0121 0.0081 0.0108 0.0270 0.0010 (0.0864) 0.09 (4.71) ** (5.367) (0.0707) 0.0006 (0.0037) (0.0030) 0.0240 (0.0083) (0.0947) (0.78) (4.47) ** (54.00) (0.0649) 0.0035 0.0012 0.0020 0.0260 0.0038 (0.0909) 0.36 (3.84) ** (53.84)	\$43.07	(0.0300)	(0.0300)		0.0079	0.0117	0.0117	(0.0417)	(0.0417)	(3.94) **		(\$1.81)	-4.1%
(0.0594) 0.0121 0.0081 0.0108 0.0270 0.0010 (0.0864) 0.09 (4.71) ** (\$3.67) (0.0707) 0.0006 (0.0037) (0.0030) 0.0240 (0.0083) (0.0947) (0.78) (4.47) ** (\$4.00) (0.0649) 0.0035 0.0012 0.0020 0.0260 0.0038 (0.0909) 0.36 (3.84) ** (\$3.84) **		(0.0412)	(0.0712)		0.0012	0.0045	0.0162	(0.0457)	(0.0874)	(4.32) **		(\$3.71)	-8.4%
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$		0.0118	(0.0594)		0.0081	0.0108	0.0270	0.0010	(0.0864)	60.0		(\$3.67)	-8.3%
(0.0649) 0.0035 0.0012 0.0020 0.0260 0.0038 (0.0909) 0.36 (3.84) ** (\$3.84)		(0.0113)	(0.0707)		(0.0037)	(0.0030)	0.0240	(0.0083)	(0.0947)	(0.78)	(4.47) **	(\$4.00)	%0.6-
		0.0058	(0.0649)		0.0012	0.0020	0.0260	0.0038	(0.0909)	0.36	(3.84) **	(\$3.84)	-8.7%

Notes and Sources:

Transcript of the June 13, 2007 advisory committee meeting regarding Zimulti (rimonabant), available on the FDA website.

[&]quot;FDA Panel Rejects Sanofi Weight Loss Drug Acomplia," Dow Jones News Service, 6/13/07, 4:08 p.m. ET.

² Data are obtained from Bloomberg, L.P.

NYSE Healthcare Index Excluding SNY. The regression is estimated over the period from February 24, 2006 through June 8, 2007. The estimation period begins with the first day's closing price, not its return. Returns are predicted from a market model that estimates the relationship between the daily returns to Sanoff ADS and the daily returns to the NYSE ARCA International Market Index Excluding SNY and See Exhibit 6.

Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level. The t-statistic must be equal to or exceed 1.97 or 1.65 in absolute value for the abnormal return to be Significance is based on the excess return's t-statistic, calculated as the daily excess return divided by the standard error of the regression over the estimation period. statistically significant at the 5% or 10% level, respectively.

Cumulative excess return t-statistics are calculated as the cumulative excess return divided by the standard error of the regression over the sample period times the square root of the number of days cumulated. Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level.

 $^{^{6}}$ Calculated using the formula: \$44.38 * [exp{ (9) + (Days/2) * s^2 } - 1], where s represents the standard error of the regression.

Sanofi-Aventis Exhibit 9.a

4005 Adjusted Net Profit of £1.44B Slightly Above Analyst Expectations of £1.43B, Operating Profit of £2.06B Below Consensus of £2.18B, and Abnormal Ordinary Shares Price Change Following the February 24, 2006 7:23 a.m. CET Announcement of Financial Results:

Guidance for Growth in FY06 EPS of Around 10%, Lower than FY05 Growth of 25.7%; and

"In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency" Regarding Rimonabant 3:00 p.m. CET Earnings Conference Call During which Defendant Le Fur States:

				FTSE	Bloomberg								
	Ordinary			Eurotop 100	Eurotop 100 Europe 500								
	Shares	Actual Ordi	Actual Ordinary Shares	Index	Index Pharmaceuticals Predicted Ordinary Shares	Predicted O	rdinary Shares	Abnormal (Abnormal Ordinary Shares	t-statistic f	t-statistic for Abnormal	Cumulativ	Cumulative Abnormal
	Closing		LN Return		Index Return	R	Return	Re	Return	Ordinary S	Ordinary Shares Return	Ordinary Shar	Ordinary Shares Price Change
Date	Price ²	Daily	Cumulative		Excl. SAN	Daily ³	Cumulative	Daily	Cumulative	Daily ⁴	Cumulative ⁵	Dollar ⁶	Percent
	(1)	(2)	(3)			(9)	(7)	(8)	(6)	(10)	(11)	(12)	(13)
		$\ln[(1)/\text{prev}(1)]$ (2) + prev(3)	(2) + prev(3)				(6) + prev(7)	(2) - (6)	(8)+prev (9)				(12)/first(1)
2/23/06	€ 72.10												
2/24/06	€ 72.50	0.0055	0.0055	0.0027	(0.0016)	0.0003	0.0003	0.0052	0.0052	0.55	0.55	€ 0.38	0.5%
2/27/06	€ 73.35	0.0117	0.0172	0.0019	0.0063	0.0038	0.0041	0.0079	0.0131	0.83	0.97	€ 0.96	1.3%
2/28/06	€ 71.40		(0.0098)	(0.0144)		(0.0146)	(0.0106)	(0.0123)	0.0008	(1.29)	0.05	€ 0.07	0.1%
3/1/06	€ 72.15	0.0104	0.0007	0.0088	0.0110	0.0097	(0.0008)	0.0007	0.0015	0.07	0.08	€ 0.12	0.2%
3/2/06	€ 71.10		(0.0140)	(0.0102)		(0.0089)	(0.0098)	(0.0057)	(0.0042)	(0.60)	(0.20)	(€ 0.29)	-0.4%

Notes and Sources:

"CET" = Central European Time. Euronext Paris closes at 5:30 p.m. CET (See https://europeanequities.nyx.com/en/trading/trading-hours-and-holidays).

³ Returns are predicted from a market model that estimates the relationship between the daily returns to Sanofi ordinary shares and the daily returns to the FTSE Eurotop 100 Index Excl. SAN and

¹ "Sanofi-Aventis 4Q Net Pft EUR456M Vs EUR1.195B," Dow Jones International News, 2/24/06 7.23 a.m. CET; "Sanofi-Aventis reports 26.0-percent profits injection," Agence France Presse, 2/24/06 10:58 a.m. CET; "Sanofi-aventis Reports Strong Growth of 25.7% in 2005 Adjusted EPS(1); Nearly 90% of synergies delivered by end 2005; Dividend increased by 26.7%," PR Newswire (U.S.), 2/24/06 1:30 p.m. CET;

[&]quot;Q4 2005 Sanofi-Aventis earnings Conference Call- Final," Voxant FD Wire, 2/24/06; "UPDATE 4-Sanofi Q4 net up 21 pct, sees H2 Acomplia launch," Reuters News, 2/24/06 7:48 a.m. CET

² Data are obtained from Bloomberg, L.P.

Euronext 100 Index Excl. SAN. The regression is estimated over the period from February 24, 2006 through June 8, 2007. The estimation period begins with the first day's closing price, not its return. 4 Significance is based on the excess return's t-statistic, calculated as the daily excess return divided by the standard error of the regression over the estimation period. See Exhibit 7.

Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level. The t-statistic must be equal to or exceed 1.97 or 1.65 in absolute value for the abnormal return to be statistically significant at the 5% or 10% level, respectively.

⁵ Cumulative excess return t-statistics are calculated as the cumulative excess return divided by the standard error of the regression over the sample period times the square root of the number of days cumulated. Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level

⁶ Calculated using the formula: €72.10 * [exp{ (9) + (Days/2) * s² } - 1], where s represents the standard error of the regression.

Sanofi-Aventis Exhibit 9.b

Abnormal Ordinary Shares Price Change Following the October 31, 2006 7:00 a.m. CET Announcement of Financial Results:

3006 Net Profit of £1.7B Above Consensus of £1.52, Sales of £6.9B Below Consensus of £7.35B Euros as a Result of Losing Plavix Sales to Generic Competition, and Slightly Raised FY06 EPS Growth Outlook from 2%, or €4.83, to "At Least 2%," Below Consensus of €4.96³; and

8:00 a.m. CET Earnings Conference Call During which Defendant Spek States, "It is Easier for Me to Say That We Have Not Submitted New Data in this Respect" Regarding the Approvable Letter for Rimonabant, and that Sanofi "Submitted October 26 a Complete Response to This Approvable Letter.... Sanofi] Will Not Speculate at All What the FDA Now Has To Do or Will Do and Within Which Timeline"

c Competition, and a see -2.6% -3.6% 4.1% -2.6% -4.0% (12)/first(1) (£2.82)(€ 2.75) (€ 1.78) $(\epsilon 1.79)$ (62.45)(1.94) * (2.77) **(1.97) ** (2.22) **(2.22) **Cumulative⁵ Ordinary Shares Return t-statistic for Abnormal Ξ (2.77) **(0.02)(1.05)(0.60)0.11 Daily⁴ (10)Abnormal Ordinary Shares (0.0366)(0.0412)0.0264(0.0265)(0.0422)Cumulative (8)+prev (9) 6 Return (0.0057)(0.0002)(0.0264)(0.0100)0.0010 (2) - (6) Daily 8 Pharmaceuticals Predicted Ordinary Shares (0.0018)0.0014 0.0032 0.0043 0.0124 Cumulative (6) + prev(7)Return (0.0018)0.0017 0.0032 0.0011 0.0081 Daily³ 9 Index Return (0.0014)0.0033 0.0084 (0.0007)0.0044 Excl. SAN Bloomberg Europe 500 **®** (0.0015)(0.0039)Eurotop 100 0.0034 0.0036 0.0117 Excl. SAN Index Return <u>4</u> (0.0334)(0.0379)0.0281) 0.0251) (0.0289)Cumulative (2) + prev(3)Actual Ordinary Shares \mathfrak{S} LN Return $\ln[(1)/\text{prev}(1)]$ (0.0083)(0.0281)(0.0045)0.0091 0.0030 Daily € 66.60 € 65.95 € 68.50 € 66.80 € 66.25 Ordinary Closing € 66.55 Shares Price² Ξ 11/1/06 11/2/06 11/3/06 90/08/01 10/31/06 11/6/06 Date

Notes and Sources:

"CET" = Central European Time. Euronext Paris closes at 5:30 p.m. CET (See https://europeanequities.nyx.com/en/trading/trading-hours-and-holidays).

"Sanofi-Aventis 3QNet Profit EUR1.7B Vs EUR1.92B," Dow Jones International News, 10/31/06 7:00 a.m. CET; "sanofi-aventis Reiterates FY 2006 EPS Outlook," Reuters Significant Developments, 10/31/06,

in sales (see "Generics lower Sanofi's profits," Handelsblatt Wirtschafts- und Finanzzeitung, 10/31/2006 and "UPDATE 4-Sanofi Q3 profit falls on Plavix, health cuts," Reuters News, 10/31/06 7:48 a.m. CET). ² There were multiple consensus figures cited in news. The one quoted in the title above is the estimate which is furthest off from the actual. Two other sources reported consensus of £1.57B in profit and £7.28B In addition, AFP reported consensus of €1.4-1.7B for profit citing a survey by AFX News (see "Sanofi profits fall as heart drug hit by competition in US," Agence France Presse, 10/31/2006 9:06 a.m. CETD.

FY06 EPS Guidance of €4.83 is calculated applying 2% growth to reported FY05 adjusted EPS of €4.74. The consensus of €4.96 implies EPS growth of around 4.6%. "Sanofi-aventis Reports Strong A different Dow Jones article reported consensus of €7.25B in sales ("UPDATE: Sanofi-Aventis Profit Falls 12% On Copycat Drugs," Dow Jones Business News, 10/31/06 10:31 a.m. CET).

"Q3 2006 Sanofi-Aventis Earnings Conference Call- Final," Voxant FD Wire, 10/31/06; "Sanofi-aventis Announces Third Quarter Sales and Earnings for 2006: Sales Growth of 2.6% on a Comparable Growth of 25.7% in 2005 Adjusted EPS(1); Nearly 90% of synergies delivered by end 2005; Dividend increased by 26.7%," PR Newswire (U.S.), 2/24/06 1:30 p.m. CET)

Basis(1); Adjusted EPS Growth of 15.0%, or 7.5% Excluding Selected Items(3)," PR Newswire (U.S.), 10/31/06 3:31 p.m. CET.

Euronext 100 Index Excl. SAN. The regression is estimated over the period from February 24, 2006 through June 8, 2007. The estimation period begins with the first day's closing price, not its return. See Exhibit 7. Returns are predicted from a market model that estimates the relationship between the daily returns to Sanofi ordinary shares and the daily returns to the FTSE Eurotop 100 Index Excl. SAN and

Data are obtained from Bloomberg, L.P.

Significance is based on the excess return's t-statistic, calculated as the daily excess return divided by the standard error of the regression over the estimation period. Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level. The t-statistic must be equal to or exceed 1.97 or 1.65 in absolute value for the abnormal return to be statistically significant at the 5% or 10% level, respectively. Cumulative excess return t-statistics are calculated as the cumulative excess return divided by the standard error of the regression over the sample period times the square root of the number of days

⁹ Calculated using the formula: €68.50 * [exp{(9) + (Days/2) * s^2} - 1], where s represents the standard error of the regression. cumulated. Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level.

% % % %

Sanofi-Aventis Exhibit 9.c

Abnormal Ordinary Shares Price Change Following the June 11, 2007 4:12 p.m. CET

Posting of Briefing Documents on FDA Website, Stating that Rimonabant Is "Associated with Statistically and Clinically Significant Weight Loss" and That the FDA is Concerned About an Increase in Psychiatric Side Effects, in Particular the Statistically Significant Increase in Suicidality

		bnormal	rice Chan	Percent	(13)	(12)/first(1)		-1.0%	-1.4%	-1.0%	-8.4%	%6.6-
		Cumulative Abnormal	Ordinary Shares Price Chan	Dollar ⁶	(12)	(1)		(6 0.66)	(6.0.96)	(€ 0.70)	(6.5.65)	(E 6.70)
		bnormal	-	Cumulative ⁵	(11)			(1.03)	(1.07)	(0.64)	(4.60) **	(4.92) **
		t-statistic for Abnormal	Ordinary Shares Return	Daily ⁴ C	(10)			(1.03)	(0.48)	0.41	(8.09) **	* (1.80)
		Abnormal Ordinary Shares	ırn	Cumulative	6)	(8)+prev (9)		(0.0098)	(0.0144)	(0.0105)	(0.0875)	(0.1047)
		Abnormal Or	Return	Daily	8)	(2) - (6)		(0.0098)	(0.0045)	0.0039	(0.0770)	(0.0172)
		linary Shares	urn	Cumulative	(2)	(6) + prev(7)		0.0091	0.0052	0.0059	0.0175	0.0291
		Predicted Ordinary Shares	Return	Daily ³	9)			0.0091	(0.0039)	0.0007	0.0116	0.0116
Bloomberg	Europe 500	Pharmaceuticals	Index Return	Excl. SAN	(5)			0.0099	(0.0020)	(0.0026)	0.0063	0.0103
		Index	Return	Excl. SAN	4)			0.0087	(0.0050)	0.0044	0.0166	0.0130
		nary Shares	eturn	Cumulative	(2) (3)	(2) + prev(3)		(0.0007)	(0.0092)	(0.0046)	(0.0700)	(0.0756)
		Actual Ordinary Shares	LN R	Daily	(2)	$\ln[(1)/\text{prev}(1)]$ (2) + prev(3)		(0.0007)	(0.0085)	0.0046	(0.0654)	(0.0056)
;	Ordinary	Shares	Closing	Price ²	Ξ		€ 67.57	€ 67.52	€ 66.95	€ 67.26	€ 63.00	€ 62.65
				Date			20/8/9	6/11/07	6/12/07	6/13/07	6/14/07	6/15/07

Notes and Sources:

"CET" = Central European Time. Euronext Paris closes at 5:30 p.m. CET (See https://europeanequities.nyx.com/en/trading/trading/hours-and-holidays).

¹ "FDA: Sanofi Weight-Loss Drug Increases Sociality," Dow Jones News Service, 6/11/07 4:12 p.m. CET.

² Data are obtained from Bloomberg, L.P.

Euronext 100 Index Excl. SAN. The regression is estimated over the period from February 24, 2006 through June 8, 2007. The estimation period begins with the first day's closing price, not its return. ³ Returns are predicted from a market model that estimates the relationship between the daily returns to Sanofi ordinary shares and the daily returns to the FTSE Eurotop 100 Index Excl. SAN and See Exhibit 7.

Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level. The t-statistic must be equal to or exceed 1.97 or 1.65 in absolute value for the abnormal return to be 4 Significance is based on the excess return's t-statistic, calculated as the daily excess return divided by the standard error of the regression over the estimation period.

⁵ Cumulative excess return t-statistics are calculated as the cumulative excess return divided by the standard error of the regression over the sample period times the statistically significant at the 5% or 10% level, respectively.

square root of the number of days cumulated. Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level. ⁵ Calculated using the formula: 667.57 * [exp{(9) + (Days/2) * s^2} - 1], where s represents the standard error of the regression.

Exhibit 9.d Sanofi-Aventis

Abnormal Ordinary Shares Price Change Following the June 13, 2007 2:00 p.m. to 10:00 p.m. CET Public Meeting of an FDA Advisory Committee and

10:08 p.m. CET unaimous "No" Vote by the FDA Advisory Committee to the Questions:

Weight Management in Individuals with a BMI of Greater or Equal to 30 and Greater than 27 when Accompanied by at Lease One Comorbid Condition?" "Based on the Current Data, Do You that Believe Rimonabant Has a Favorable Risk/Benefft Profile and Should be Approved for the Indication of

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Cumulative Abnormal	Ordinary Shares Price Change	Percent	(13)	(12)/first(1)			-7.4%	%0.6-	-9.4%	%6.8-	%8.6-
Cumulativ	Ordinary Shan	Dollar ⁶	(12)				(£ 4.98)	(66.04)	(66.30)	(€ 6.01)	(€ 6.61)
r Abnormal	Ordinary Shares Return (Cumulative ⁵	(11)				** (8.09)	(7.00) **	** (5.97)	(4.92) **	(4.87) **
t-statistic for Abnormal	Ordinary Sh	Daily ⁴	(10)				** (60.8)	(1.80) *	(0.45)	0.49	(1.05)
Abnormal Ordinary Shares	Return	Cumulative	(6)	(8)+prev (9)			(0.0770)	(0.0942)	(0.0984)	(0.0937)	(0.1037)
Abnormal C	Re	Daily	8)	(2) - (6)			(0.0770)	(0.0172)	(0.0042)	0.0047	(0.0100)
Predicted Ordinary Shares	Return	Cumulative	6	(6) + prev(7)			0.0116	0.0232	0.0176	0.0139	0.0166
		Daily ³	(9)				0.0116	0.0116	(0.0055)	(0.0037)	0.0027
Bloomberg Europe 500 Pharmaceuticals	Index Return	Excl. SAN	(5)				0.0063	0.0103	(0.0064)	(0.0037)	0.0020
FTSE Eurotop 100 Index	Return	Excl. SAN	4				0.0166	0.0130	(0.0040)	(0.0031)	0.0038
Actual Ordinary Shares	teturn	Daily Cumulative	(3)	n[(1)/prev(1)] (2) + prev(3)			(0.0654)	(0.0710)	(0.0808)	(0.0798)	(0.0871)
Actual Ord	LN Return	Daily	(2)	$\ln[(1)/\mathrm{prev}(1)]$			(0.0654)	(0.0056)	(0.0098)	0.0010	(0.0073)
Ordinary Shares	Closing	Price ²	(1)			€ 67.26	€ 63.00	€ 62.65	ϵ 62.04	ϵ 62.10	€ 61.65
		Date				6/13/07	6/14/07	6/15/07	6/18/07	6/19/07	6/20/07

Notes and Sources:

"CET" = Central European Time. Euronext Paris closes at 5:30 p.m. CET (See https://europeanequities.nyx.com/en/trading/trading/hours-and-holidays).

Significance is based on the excess return's t-statistic, calculated as the daily excess return divided by the standard error of the regression over the estimation period.

Transcript of the June 13, 2007 advisory committee meeting regarding Zimulti (rimonabant), available on the FDA website.

[&]quot;FDA Panel Rejects Sanofi Weight Loss Drug Acomplia," Dow Jones News Service, 6/13/07, 10:08 p.m. CET.

² Data are obtained from Bloomberg, L.P.

Euronext 100 Index Excl. SAN. The regression is estimated over the period from February 24, 2006 through June 8, 2007. The estimation period begins with the first day's closing price, not its return. Returns are predicted from a market model that estimates the relationship between the daily returns to Sanofi ordinary shares and the daily returns to the FTSE Eurotop 100 Index Excl. SAN and See Exhibit 7.

Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level. The t-statistic must be equal to or exceed 1.97 or 1.65 in absolute value for the abnormal return to be statistically significant at the 5% or 10% level, respectively.

Cumulative excess return t-statistics are calculated as the cumulative excess return divided by the standard error of the regression over the sample period times the square root of the number of days cumulated. Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level.

Calculated using the formula: $667.26 * [exp{ (9) + (Days/2) * s^2 } - 1]$, where s represents the standard error of the regression.

Exhibit 10 Sanofi-Aventis Summary of Event Study Findings for Sanofi ADS

	Length													
	of Event						M	Market Model ²	2					
Event Date	Window ¹ Model 1	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6	Model 7				Model 11	Model 12	Model 13
(1)	(2)	(3)	(4)		! I	£)		(6)	(10)	(11)	(12)	(13)	(14)	(15)
2/24/2006	1 day													
Abn. LN Return		0.0106	0.0113	0.01111	0.0099	0.0146	0.0143	0.0131	0.0128	0.0070	0.0122	0.0128	0.0131	0.0137
Abn. ADS Price Change (\$)		\$0.46	\$0.49	\$0.48	\$0.43	\$0.63	\$0.62	\$0.57	\$0.55	\$0.30	\$0.53	\$0.55	\$0.57	\$0.59
Abn. ADS Price Change (%)		1.07%	1.15%	1.13%	1.00%	1.48%	1.45%	1.33%	1.30%	0.71%	1.23%	1.30%	1.32%	1.38%
t-statistic		0.95	0.99	1.00	06.0	1.30	1.32	1.13	1.12	0.61	1.16	1.20	1.24	1.26
10/31/2006	1 day													
Abn. LN Return		(0.0194)	(0.0185)	(0.0213)	(0.0212)	(0.0123)	(0.0132)	(0.0130)	(0.0150)	(0.0216)	(0.0168)	(0.0154)	(0.0163)	(0.0142)
Abn. ADS Price Change (\$)		(\$0.84)	(\$0.80)	(\$0.92)	(\$0.91)	(\$0.53)	(\$0.57)	(\$0.56)	(\$0.65)	(\$0.93)	(\$0.72)	(\$0.66)	(\$0.70)	(\$0.61)
Abn. ADS Price Change (%)		-1.92%	-1.83%	-2.11%	-2.09%	-1.22%	-1.31%	-1.28%	-1.48%	-2.13%	-1.66%	-1.52%	-1.61%	-1.41%
t-statistic		(1.75) *	(1.62)	(1.92) *	(1.94) *	(1.10)	(1.22)	(1.12)	(1.31)	(1.87) *	(1.60)	(1.45)	(1.54)	(1.32)
6/11/2007 Abn. LN Return	1 day	(0.0092)	(0.0086)	(0.0086)	(0.0088)	(0.0128)	(0.0098)	(0.0092)	(0.0076)	(0.0106)	(0.0095)	(0.0097)	(0.0095)	(0.0096)
Abn. ADS Price Change (\$) Abn. ADS Price Change (%)		(\$0.41)	(\$0.39) -0.85%	(\$0.39) -0.85%	(\$0.40)	(\$0.57) -1.26%	(\$0.44)	(\$0.41) -0.91%	(\$0.34)	(\$0.48)	(\$0.43)	(\$0.44)	(\$0.43)	(\$0.43) -0.95%
t-statistic		(0.83)	(0.76)	(0.77)	(0.81)	(1.14)	(0.90)	(0.79)	(0.66)	(0.91)	(0.91)	(0.91)	(0.89)	(0.89)
6/13/2007 Abn. LN Return	2 days	(0.0600)	(0.0904)	(0.0897)	(0.0888)	(0.0810)	(0.0819)	(0.0814)	(0.0814)	(0.0821)	(0.0874)	(0.0874)	(0.0874)	(0.0852)
Abn. ADS Price Change (\$)		(\$3.85)	(\$3.83)	(\$3.80)	(\$3.77)	(\$3.45)	(\$3.49)	(\$3.46)	(\$3.46)	(\$3.49)	(\$3.71)	(\$3.71)	(\$3.71)	(\$3.62)
Abn. ADS Price Change (%)		-8.68%	-8.63%	-8.57%	-8.48%	-7.77%	-7.85%	-7.81%	-7.81%	-7.87%	-8.36%	-8.36%	-8.36%	-8.16%
t-statistic		(5.80) **	(5.60) **	(5.70) **	(5.75) **	(5.10) **	(5.34) **	(4.96) **	(5.02) **	(5.02) **	(5.90) **	(5.80) **	(5.84) **	(5.58) **

Notes and Sources:

Data are from Bloomberg Finance L.P.

¹ For each event date, the length of event window is the same across all market models in this case. In theory, the length of event window can be different across models.

² See Exhibit 6 for specifications of each market model.

Sanofi's ADS LN returns are predicted using a market model that regresses daily LN return to Sanofi ADS against the index (indices) daily LN return(s). Abnormal LN Return = Actual Return - Predicted Return.

Daily or Cumulative Abnormal ADS price change (\$) = Price on Day Prior to Event Date * [exp{ Abnormal LN Return + (d/2) * s^2 } - 1], where d represents the length of event window in days, and s represents the standard error of the regression.

Daily or Cumulative Abnormal ADS price change (%) = Abnormal ADS Price Change (\$) / Price on Day Prior to Event Date. t-statistic = Abnormal LN Return / Standard Error of the Equation.

Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level.

Exhibit 11 Sanofi-Aventis Summary of Event Study Findings for Sanofi Ordinary Shares

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Length

	of Event			I	Market Model ³			
Event Date ¹	Window ²	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6	Model 7
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
2/24/2006	1 day							
Abn. LN Return		0.0015	0.0037	0.0028	0.0071	0.0076	0.0074	0.0052
Abn. Ordinary Shares Price Change (ϵ)		€ 0.11	€ 0.27	€ 0.20	€ 0.52	€ 0.56	€ 0.54	€ 0.38
Abn. Ordinary Shares Change (%)		0.16%	0.38%	0.28%	0.72%	0.77%	0.75%	0.53%
t-statistic		0.15	0.38	0.28	0.71	0.74	0.70	0.55
10/31/2006	1 day							
Abn. LN Return		(0.0275)	(0.0265)	(0.0274)	(0.0268)	(0.0259)	(0.0235)	(0.0264)
Abn. Ordinary Shares Price Change (€)		(€ 1.85)	(€ 1.79) -2.61%	(€ 1.85)	(€ 1.81) -2.64%	(€ 1.75)	(€ 1.59) -2.32%	(€ 1.78) -2.60%
Abn. Ordinary Shares Change (%) t-statistic		-2.70% (2.72) **	(2.69) **	-2.70% (2.72) **	(2.67) **	-2.56% (2.53) **	(2.24) **	(2.77) **
6/11/2007	1 day							
Abn. LN Return		(0.0072)	(0.0074)	(0.0068)	(0.0094)	(0.0047)	(0.0018)	(0.0098)
Abn. Ordinary Shares Price Change (€)		(€ 0.48)	(€ 0.49)	(€ 0.46)	(€ 0.63)	(€ 0.31)	(€ 0.12)	(€ 0.66)
Abn. Ordinary Shares Change (%)		-0.71%	-0.73%	-0.68%	-0.93%	-0.46%	-0.18%	-0.97%
t-statistic		(0.71)	(0.75)	(0.68)	(0.94)	(0.45)	(0.18)	(1.03)
6/14/2007	1 day							
Abn. LN Return		(0.0817)	(0.0786)	(0.0803)	(0.0710)	(0.0676)	(0.0661)	(0.0770)
Abn. Ordinary Shares Price Change (€)		(€ 5.27)	(€ 5.08)	(€ 5.19)	(€ 4.60)	(€ 4.39)	(€ 4.30)	(€ 4.98)
Abn. Ordinary Shares Change (%)		-7.84%	-7.55%	-7.71%	-6.84%	-6.53%	-6.39%	-7.41%
t-statistic		(8.10) **	(7.98) **	(7.99) **	(7.08) **	(6.59) **	(6.28) **	(8.09) **

Notes and Sources:

Data are from Bloomberg Finance L.P.

Sanofi's ordinary shares LN returns are predicted using a market model that regresses daily LN return to Sanofi ordinary shares against the index (indices) daily LN return(s).

Abnormal LN Return = Actual Return - Predicted Return.

Daily or Cumulative Abnormal Ordinary Shares Change (ϵ) = Price on Day Prior to Event Date * [exp{ Abnormal LN Return + (d/2) * s^2 } - 1], where d represents the length of event window in days, and s represents the standard error of the regression.

Daily or Cumulative Abnormal Ordinary Shares Price Change (%) = Abnormal Ordinary Shares Price Change (€) / Price on Day Prior to Event Date. t-statistic = Abnormal LN Return / Standard Error of the Equation.

Two stars indicate significance at the 5% level, and one star indicates significance at the 10% level.

¹ See Exhibit 3.a-3.d for news on each event date. Time stamps of news are available here:

[&]quot;Sanofi-Aventis 4Q Net Pft EUR456M Vs EUR1.195B," Dow Jones International News, 2/24/06 7:23 a.m. Central European Time ("CET");

[&]quot;Sanofi-Aventis 3QNet Profit EUR1.7B Vs EUR1.92B," Dow Jones International News, 10/31/06 7:00 a.m. CET;

[&]quot;FDA: Sanofi Weight-Loss Drug Increases Sociality," Dow Jones News Service, 6/11/07 4:12 p.m. CET;

[&]quot;FDA Panel Rejects Sanofi Weight Loss Drug Acomplia," Dow Jones News Service, 6/13/07, 10:08 p.m. CET.

Euronext Paris closes at 5:30 p.m. CET (See https://europeanequities.nyx.com/en/trading/trading-hours-and-holidays).

² For each event date, the length of event window is the same across all market models in this case. In theory, the length of event window can be different across models.

³ See Exhibit 7 for specifications of each market model.

Exhibit 12 Sanofi-Aventis

10 of 38 Analysts Published that Rimonabant Might Pose a Risk of Suicidality January 1, 2006 through June 10, 2007

	Analyst (1)	Report Date (2)	Report Title (3)	Quote (4)
1.	Bank of America	03/16/07	Favorable Risk/Reward; Mgmt Meetings Highlight Pipeline Opps	Acomplia Remains Most Significant Pipeline Opportunity. Despite a conservative and increasingly unpredictable FDA (as seen with the recent Galvus delay), we continue to anticipate a US approval for Acomplia in late July. Based on the side profile (including suicide rate) seen in the 300,000 European patients prescribed Acomplia since its 3Q/06 European launch, we remain comfortable with Acomplia's safety profile. We also believe an advisory panel meeting on the drug (potentially June 13-14) is possible Following recent meetings with sanofi-aventis management, we remain encouraged by the
				breadth of sanofi's pipeline Based upon the side profile (including suicide rate) seen in the 300,000 European patients prescribed Acomplia since its 3Q/06 European launch, we remain comfortable with Acomplia's safety profile and anticipate a late July approval.
2.	Bernstein Research	01/18/06	Sanofi-Aventis: Acomplia Soon to Promote Fat Gains from Fat Loss; Reiterate €4.4 bn in 2010	Exhibit 9 Acomplia vs. Xenical vs. Meridia for Side Effects of Concern: Which is Worst for Which Adverse Event? Acomplia (Nausea, Anxiety), Xenical (Gastrointestinal Effects), Meridia (Cardiovascular and CNS Effects)
				In terms of other side effects, Meridia has also been associated with dry mouth, insomnia, dizziness, paresthesia, somnolence, and mental / mood changes (e.g. excitement, restlessness, confusion, emotional lability, anxiety, depression, and rare thoughts of suicide). The Meridia label states: "Cases of depression, suicidal ideation and suicide have been reported rarely in patients on [Meridia] treatment. However, a relationship has not been established between the occurrence of depression and/or suicidal ideation and the use of [Meridia]. If depression occurs during treatment with [Meridia], further evaluation may be necessary." Many cite mood changes associated with Acomplia as reason enough for delay or rejection. We note that Meridia has been approved with CNS side effects that to us are worse than those for Acomplia
	Bernstein Research	06/22/06	Sanofi-Aventis: Acomplia Approved in E.U.; U.K. Launch in July; Certainty a Plus for Sentiment and Potentially Revisions	On Wednesday, Sanofi announced that the European Commission has granted marketing authorization in all 25 European member states for Acomplia (Zimulti, rimonabant) The Acomplia wording for patients with uncontrolled serious psychiatric illnesses is no surprise given Acomplia's CNS activity. The limitation does not seem to rule out use in patients with controlled serious psychiatric illnesses. As such, we do not see the limit as a major obstacle: After all, common sense dictates a patient with a serious psychiatric illness, e.g. who has psychosis or suicidal thoughts, should not be put on Acomplia first but should be treated and controlled prior to starting Acomplia or a great number of other therapies.

Exhibit 12 Sanofi-Aventis

10 of 38 Analysts Published that Rimonabant Might Pose a Risk of Suicidality January 1, 2006 through June 10, 2007

	Analyst (1)	Report Date (2)	Report Title (3)	Quote (4)
3.	Citigroup	02/08/06	Obese Obsessions (Mission Acomplia I)	Acomplia: Safety Before Efficacy The principle reason previous diet drugs have not been successful are side effects which make taking them chronically unreasonable. Furthermore the FDA's more conservative approach following the antidepressants and suicide link and the relationship between Vioxx and heart attacks / strokes raises the safety bar even higher. This is compounded by the massive anticipated demand for obesity drugs and that it is healthy people not patients that would want to take them. Furthermore the benefits of weight loss can be achieved safely by sensible dieting and exercise. Hence we expect the regulatory emphasis on obesity drugs such as Acomplia is safety first.
				Depression & anxiety The prevalence of depression amongst obese patients is estimated at over 20%. However all the RIO trials specifically excluded neurological or psychological illness, a history of two or more episodes of depression, or suicide attempt. Since the trial population is not accurately representative of the target population, the possibility of a suicide in a depressed person who also took Acomplia is raised. Furthermore concomitant use of antidepressants or neuroleptic drugs was not permitted in the RIO trials, but the probability of concomitant use is raised, even if a specific contradiction is forced on to the label. One case of suicide on Acomplia in obesity would be disastrous for Sanofi-Aventis and the FDA, especially in the post Vioxx era.
				Figure 11 Risk-benefit profile for Acomplia's possible indications Chronically is there an increased suicide risk in depressed patient, BMI <30, where minimal benefit present Concern risk outweighs benefit
	Citigroup	06/08/07	Acomplia[']s Judgment Day	Summary ➤ Panel documents likely to be incrementally negative on safety — Panel documents are expected no later than 8am EDT June 12. Since this will for the first time describe the FDA's concerns along with the data submitted, we expect this to reveal concerns on safety, adversely affecting the ADR on the 12th. ➤ Risk-averse FDA would need a unanimous panel — Zimulti is being reviewed again by the same FDA division that rejected Novartis's Galvus on monkey skin toxicity, despite no human cases. With fears of what sequlae Zimulti-induced depression could have in an obesity indication with a 20% background rate of depression, FDA would need unanimous Panel ratification to validate approval.
				Safety first — Predicted side effects now seen in humans: Memory loss, convulsion and hallucinations, and a case of suicide in unclear circumstances. Considering modest weight loss and some weight regained despite steady use, long-term risk-benefit makes us err on the side of caution going into the panel.

Exhibit 12 Sanofi-Aventis

10 of 38 Analysts Published that Rimonabant Might Pose a Risk of Suicidality January 1, 2006 through June 10, 2007

Analyst (1)	Report Date (2)	Report Title (3)	Quote (4)
			If Zimulti does not get through this time, its next chance is 2012 Side effects predicted in our 8th February report "Mission Acomplia I" now seen in humans: Memory loss, convulsion and hallucinations along with a case of suicide in unclear circumstances. Combining this with only modest weight loss, some weight regain despite continuous use, the long term risk-benefit makes us err on the side of caution going into the panel.
			Safe? Parasomnias, hallucinations, memory loss, depression and suicide Still unsafe: With safety concerns overhanging any eventual sales of Acomplia in weight-loss even if it finally secures FDA approval after a resubmission, we remain skeptical of Acomplia's commercial prospects. The FDA's draft guidance for obesity drugs states: "Because all drug and biological therapies impose some risk for adverse events, the use of a weight-management product should be contemplated only after a sufficient trial of lifestyle modification has failed and the risks of excess adiposity and the anticipated benefits of weight loss are expected to outweigh the known and unknown risks of treatment with a particular weight-management product." (footnotes omitted)
			Suicide in unclear circumstances "A completed suicide in unclear circumstances". The major fear with the depressive side effects of Acomplia is that taking the drug may precipitate suicide, especially since 20% of obese people are also clinically depressed. However depressed patients were excluded from the entire trial population, making for a non representative trial sample. Anecdotal reports in the media cite examples of suicidal ideation while on Acomplia. As Acomplia is given to more people in trials or in Europe, the prospects of a second suicide case rise(footnotes omitted)
4. Cowen & Co. (SG Cowen)	04/26/06	Investment Controversies Series - Major Pharmaceuticals Physician - Survey Suggests SNY's Rimonabant Will Be A Heavyweight	Opposing View: Depression will be a major hurdle to physician prescribing and significantly limit Rimonabant's potential. Potential suicidal behavior is particularly troubling. The recent approvable letter for Rimonabant heightened concern that the FDA is uneasy about the drug's side-effect profile. Given concerns about depression, we asked physicians to estimate the percentage of patients on antidepressants to whom they would prescribe Rimonabant Endocrinologists were the least optimistic, noting that they would put about 33% of depressed patients on Rimonabant. Most physicians agreed that they would probably not prescribe Rimonabant to a small percentage of clinically depressed patients with either a history of major depression or suicidal ideation. That physicians were comfortable prescribing the drug to patients with mild-to-moderate depression is a positive, however. Endocrinologist: In treating depressed patients, I will weigh all the risks. There is a wide range
			of depression. I will not give it to patients that are diagnosed with major depression. For those

first, I would look for an absence of suicidal ideation...

with controlled depression, I would give Rimonabant only under certain circumstances:

Exhibit 12 Sanofi-Aventis

10 of 38 Analysts Published that Rimonabant Might Pose a Risk of Suicidality January 1, 2006 through June 10, 2007

	Analyst Repo (1) (2)		Report Title (3)	Quote (4)
				Cardiologist: What does the level of depression mean especially after the juvenile cases of suicide on the ADHD medications. I think that is what is probably holding it up. I am very familiar with their data and I have highlighted this as one of the areas of great attention.
5.	Exane BNP Paribas	06/22/06	Acomplia approved in the EU	The risk on Acomplia stems from its depression safety signal. It is quite manageable because it will be screened by prescribers and, if it appears, can be stopped simply by discontinuing treatment. The risk is that patients may commit suicide while on Acomplia: although there appears to have been no imbalance of such cases vs. placebo in clinical trials, managing communication on this issue will be key.
	Exane BNP Paribas	08/17/06	Update on the Plavix saga and Sanofi- Aventis's other moving parts	In a worst-case scenario, Acomplias launch will be a failure, i.e. its sales will be equivalent to those of Roches Xenical. This would reduce our 2010e EPS by 6%. The risk on Acomplia stems from its depression safety signal. The risk is quite manageable because prescribers will screen for the signal, and if it appears, treatment can simply be discontinued. The risk is that patients may commit suicide while on Acomplia. Although there appears to have been no imbalance in the number of cases among subjects taking Acomplia versus those taking placebos in clinical trials, managing communication on this issue will be key.
	Exane BNP Paribas	09/01/06	Preliminary injunction for Plavix, non- approvable letter for Dronedarone	The risk on Acomplia stems from its depression safety signal. The risk is quite manageable because prescribers will screen for the signal, and if it appears, treatment can simply be discontinued. The risk is that patients may commit suicide while on Acomplia. Although there appears to have been no imbalance in the number of cases among subjects taking Acomplia versus those taking placebos in clinical trials, managing communication on this issue will be key.
6.	Goldman Sachs	02/10/06	Acomplia PDUFA date imminent	Other examples for where there is support for a role for cannabinoids in the regulation of various physiological processes, and where blockade could unleash unusual side effects, include: • Depression and anxiety – risk of suicide? We note that cases of depression and suicide have been reported rarely in post-marketing studies for patients taking Meridia, although a relationship to drug has not been established. Given the number of drop-outs for CNS side effects for Acomplia in clinical trials this could become apparent long term. Meridia does not have a boxed warning for suicide. Xenical's label has no comments on suicidal ideation or suicide. Any negative press around such events for Acomplia – should they arise during post-marketing studies – would likely hit the share price but are unlikely to be detrimental to the product. • Ectopic pregnancies • Cardiac implications

Exhibit 12 Sanofi-Aventis

10 of 38 Analysts Published that Rimonabant Might Pose a Risk of Suicidality January 1, 2006 through June 10, 2007

Analyst	Report Date	Report Title	Quote
(1)	(2)	(3)	(4)
7. Merrill Lynch	01/31/06	Revisiting Acomplia	Although the overall safety profile appears acceptable, the FDA may be concerned that there might be selected as yet unidentified patients who could have severe adverse reaction to the drug. We note that this concern was raised by the American Heart Associations appointed discussant of the RIO-North America data who noted that "even though the safety profile of rimonabant (Acomplia) appeared favorable, there might be selected patients, unidentified to date, who have adverse effects to this compound." In addition, we highlight that the FDA may be more cautious in its view of Acomplia following the issue of suicidal tendency in adolescents with certain marketed anti-depressants (e.g. GSK's Paxil), which surfaced last year.
			Key concern – potential for unknown outliers with severe reaction However, our key concern at present is that there is no detailed published data on the stratification for the severity of depression occurring i.e. to answer the question of whether there is a small (but significant) subset of patients that experience severe depression / suicidal tendency with Acomplia therapy. Although the company and lead investigators of the studies do not believe these CNS issues to be of significant concern, the FDA may take a more cautious view.
8. Morgan Stanley	11/03/06	3Q not pretty, Acomplia and Plavix outlook remains opaq	Despite recent US Acomplia filing, we see '06 approval as improbable. We continue to expect the FDA to grant Acomplia class II resubmission, pushing potential approval date into 2Q 2007. Initial UK script trends are encouraging. Suicides in Acomplia patients reported in Canada but "company claims event rate in placebo group significantly lower Acomplia treated patients."
9. Prudential Equity Group, LLC	05/10/06	SNY: Updates from Meeting with U.S. Management Team	We asked SNY about what sort of "risk management" program the product may have to launch with - we have been under the impression that something more formal than usual post-marketing surveillance (like a patient registry) may be required by FDA. SNY said a patient registry is possible, but probably unlikely. SNY continued to drive home the message about wanting the uptake of rimonabant to be slow and measured. In our view, this would be wise given the potential for rimonabant to cause mood disturbances: usage of the product in inappropriate patient populations could cause the risks of rimonabant (ie depression) to exceed its benefits (ie weight loss), in our opinion. As it is, rimonabant has the trappings of running into various "issues" once it is launched: for example, any patients taking rimonabant who commit suicide could warrant heavy scrutiny and cause negative headlines that impact commercial performance. This is the sort of situation SNY likely wishes to avoid.

Exhibit 12 Sanofi-Aventis

10 of 38 Analysts Published that Rimonabant Might Pose a Risk of Suicidality January 1, 2006 through June 10, 2007

Analyst (1)	Report Date (2)	Report Title (3)	Quote (4)
10. UBS	02/13/07	Wait watchers	Uncertainty remains as to the approvability of rimonabant/Acomplia in the US. A higher
Investment		continued	incidence of depression associated with the product leading to a possible increase in risk of
Research			suicidal behaviour may pose a potential hurdle to approval for the compound. The delay does not increase the probability of approval.
UBS	02/14/07	Risk, but what	We continue to believe that the higher incidence of depression associated with Acomplia,
Investment		return?	leading to a possible increase in the risk of suicidal behaviour, may pose a potential hurdle
Research			to approval. The delay hence does not increase the probability of approval and serves as a reminder of the risk to Acomplia and the growth of Sanofi-Aventis.

Notes and Sources:

Exhibit includes the results of an electronic search for "suicid" among our sample of available analyst reports. Quotes stating that severely depressed or suicidal patients were excluded from rimonabant clinical trials are not listed here. Sample of reports searched includes (a) the initial set of analyst reports provided by counsel; (b) additional reports known to have been published in the 5 calendar days beginning with a challenged statement or the corrective disclosure (i.e. February 24-28, 2006, October 31-November 4, 2006, and June 11-June 17, 2007); (c) additional reports sufficient to ensure that we had at least one report (if extant) by each of the 38 analysts from each of 1H2006, 2H2006, and 1H2007 (but before June 11, 2007); (d) additional reports sufficient to ensure that for each analyst for whom we had a report issued from June 11 through June 17, 2007, we had that analyst's last report published prior to June 11, 2007; and (e) the approximately 1,470 reports that were produced in this litigation pursuant to subpoenas from Plaintiffs and Defendants before March 19, 2012 by the following analysts: Cowen & Co., Exane BNP Paribas, Goldman Sachs, Morgan Stanley, Prudential Equity Group, Raymond James, Societe Generale, and UBS Investment Research. Reports that were not obtained from counsel were purchased via Thomson Investext or Reuters Knowledge.

Exhibit 13 Sanofi-Aventis

25 of 38 Analysts Published About Rimonabant's CNS/Psychiatric, Depression, or Suicidality Side Effects Prior to the FDA's June 11, 2007 Release of Briefing Documents January 1, 2006 through June 10, 2007

Mentioned This Rimonabant Side Effect ² Suicidality Psychiatric/ Psychiatric/CNS Psychiatric/CNS, Suicidality ³ CNS 4 Analyst 1 Depression or Depression or Depression (3) (1) **(2)** (4) (5) **(6)** (3) or (4) (2), (3) or (4) 1. Ahorro Corporacion Financiera S.V.B 5 2. Aurel BGC (Aurel Leven) X X X X 3. Bank of America X X X X 4. Barclays Capital (Lehman Brothers) X X X X 5. Bear Stearns X X X X X X X X X 6. Bernstein Research X X X X 7. Cazenove X^6 8. Cheuvreux X X 9. Citigroup X X X X X X Х 10. Cowen & Co. (SG Cowen) X Χ Χ 11. Credit Suisse X Χ Χ 12. Deutsche Bank X X X X 13. Dresdner Kleinwort 14. DZ Bank AG 15. Exane BNP Paribas X Χ X X Χ 16. Financiele Diensten Amsterdam Bv (FDA) 17. Goldman Sachs X X X X X 18. Helvea X 19. HSBC Global Research Χ Χ X 20. IIR Group X X X 21. ING 22. JP Morgan Х Х X Χ 23. Jyske Bank X X X X 24. Kelper 25. Leerink Swann 26. Macquarie (Oppenheim) X 27. Merrill Lynch Χ Χ X Χ X X X X X 28. Morgan Stanley 29. MorningStar 30. NATIXIS (NATEXIS or IXIS) 31. ODDO X 32. Prudential Equity Group, Inc. X Χ Χ Χ 33. Raymond James Euro Equities X X X X 34. RBS (ABN-AMRO) Χ Χ Χ Χ 35. Redburn Partners LLP X X X X 36. Societe Generale X X X X 37. UBS Investment Research X X X X Χ 38. WestLB Equity Markets No. of Analysts with at Least One Mention 10 23 23 25 25

Exhibit 13 Sanofi-Aventis

25 of 38 Analysts Published About Rimonabant's CNS/Psychiatric, Depression, or Suicidality Side Effects Prior to the FDA's June 11, 2007 Release of Briefing Documents January 1, 2006 through June 10, 2007

Notes and Sources:

- ¹ See Appendix 3 for list of analysts. Limited to reports published before the release of the FDA Briefing Documents on June 11, 2007.
- An electronic search of available analyst reports was conducted using the following search terms in the context of Rimonabant: "suicid", "psychiatric", "CNS", "central nervous system" and "depress". Sample of reports searched includes (a) the initial set of analyst reports provided by counsel; (b) additional reports known to have been published in the 5 calendar days beginning with a challenged statement or the corrective disclosure (i.e. February 24-28, 2006, October 31-November 4, 2006, and June 11-June 17, 2007); (c) additional reports sufficient to ensure that we had at least one report (if extant) by each of the 38 analysts from each of 1H2006, 2H2006, and 1H2007 (but before June 11, 2007); (d) additional reports sufficient to ensure that for each analyst for whom we had a report issued from June 11 through June 17, 2007, we had that analyst's last report published prior to June 11, 2007; and (e) the approximately 1,470 reports that were produced in this litigation pursuant to subpoenas from Plaintiffs and Defendants before March 19, 2012 by the following analysts: Cowen & Co., Exane BNP Paribas, Goldman Sachs, Morgan Stanley, Prudential Equity Group, Raymond James, Societe Generale, and UBS Investment Research. Reports that were not obtained from counsel were purchased via Thomson Investext or Reuters Knowledge.
- ³ See Exhibit 12.
- ⁴ CNS = Central Nervous System
- 5 Identified one quote; it mentions depression in the context of encouraging findings in SERENADE study. Conservatively, this quote was excluded from the exhibit.
- ⁶ Identified one quote; it mentions valuation model and sales projections for Acomplia. "The safety profile seen in the RIO studies plus reassuring Sanofi comments we commented on last December, and the absence of advisory committees, make us look for a straight approval in the US in obesity/smoking cessation with mention of activity on various cardiovascular risk factors (decision expected in February, presumably before the 24th, release date for FY-05 earnings): we now assume a 100% success rate vs. 80% (unchanged 4% penetration rate to account for potential restriction for patients with depression, and reimbursement issues)."
- ⁷ Identified one quote; it comments on positive findings regarding depression side-effects in Japanese patients as compared to the Western population. Conservatively, this quote was excluded from the exhibit.

Exhibit 14
Sanofi-Aventis
Analysts' Comments About Rimonabant's Prospects for Approval
Before and After the June 11, 2007 Release of the FDA Brief

Following the Release of FDA Brief:

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			Did Analyst's	Approval	View	Become	Less	Favorable?	(7)	Yes
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					6/11 or 6/12 Report Following the Release of 6/11 FDA Brief			Quote	(5)	Yesterday Food & Drug Administration (FDA) briefing documents confirmed our suspicions: The approvable letter in 2006 was due to the FDA's "concern about [an] increased frequency of psychiatric adverse events, including suicidality". Risk-Benefit Ratio Skewed To Downside— Considering modest weight loss and some weight regain, along with the concern of widespread use despite a risk management program, the risk-benefit is unclear. This could lead to a mixed at best Panel and an approvable letter while the FDA waits for risk benefit proof from the 17,000 patient mortality trial (CRESCENDO) due in 2010.
					6/11 or 6	Report	Date and	Title	(4)	FDA states Zimulti (Acomplia) doubles suicidality rate in Advisory Committee briefing documents
					Last Report Prior to the Release of 6/11 FDA Brief ²			Quote	(3)	Risk-averse FDA would need a unanimous panel With fears of what sequlae Zimulti-induced depression could have in an obesity indication with a 20% background rate of depression, FDA would need unanimous Panel ratification to validate approval. Side effects predicted in our 8th February report "Mission Acomplia I" now seen in humans: Memory loss, convulsion and hallucinations along with a case of suicide in unclear circumstances. Combining this with only modest weight loss, some weight regain despite continuous use, the long term risk-benefit makes us err on the side of caution going into the panel. Risks the risk that Acomplia will not achieve FDA approval in 2007 has risen markedly after the failure of Sanofi-Aventis's first NDA submission. With the initial demand for Acomplia likely to be massive, the known neuro-psychiatric side effects may make it difficult for the FDA to see a positive risk-benefit ratio.
					Last R	Report	Date and	Title	(2)	6/8/07 Acomplia[']s Judgment Day
								Analyst 1	(1)	. Citigroup

Exhibit 14
Sanofi-Aventis
Analysts' Comments About Rimonabant's Prospects for Approval
Before and After the June 11, 2007 Release of the FDA Brief

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					6/11 or 6/12 Report $\overline{\text{Following}}$ the Release of 6/11 FDA Brief			Quote	(5)	The FDA briefing books have raised concerns over	serious adverse events associated with Zimulti.	Given other therapeutic options for weight loss,	and a lack of data to support clinical outcomes	(mortality etc.), non-approval is clearly a	possibility. Under a best case scenario (approval	based upon patient registration/boxed warnings),	Zimulti revenues are likely to fall short of consensus	forecasts (Euro 1.5bn).		In the absence of clinical trial data or evidence	supporting a clinical outcome benefit there remains	significant risk (>30%) that the FDA panel does not	recommend Zimulti for approval.		
					6/11 or 6/	Report	Date and	Title	(4)	6/11/07	FDA briefing	books	highlight	Zimulti safety	concerns										
					Last Report Prior to the Release of 6/11 FDA Brief ²			Quote	(3)	The FDA concerns over CNS AEs likely relate to the	CB-1 antagonist class, rather than Acomplia	specifically. Based on P3 data, we believe Acomplia	is >50% likely to gain FDA approval, but strict	labeling is likely to restrict its use to an obesity	agent rather than a diabetes product										
					Last Re	Report	Date and	Title	(2)	5/3/07	A good start to	2007; minimal	changes to	EPS forecasts											
								Analyst 1	(1)	2. Deutsche	Bank														

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Exhibit 14
Sanofi-Aventis
Analysts' Comments About Rimonabant's Prospects for Approval

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		1/11 on 6/19 Donnest Dollanding the Delegae of 6/11 DDA Duist	12 Report Following the Kelease of 0/11 FDA Drief			Quote	(5)	On balance, we still think FDA comittee are likely to vote to approve the drug with a possible black box warning on suicide risk and a contraindication in any high risk populations for neurogical/psychiatric conditions. While the CNS side effects do seem to be significant, we think on balance they should be manageable.
		(/) no (//)	0/11 01 0/	Report	Date and	Title	(4)	Acomplia Efficacy fine. Possible suicide issue. On balance, drug still likely to be approved. Buy ahead of meeting
		I and Daname Dulan to the Delance of 6/11 CDA Dulas 2	r Report From to the Release of 0/11 FDA Brief			Quote	(3)	On June 13, an FDA Advisory committee will meet to review Sanoff's Zimulti/Acomplia (obesity). We believe the market is overly negative, so we would buy ahead of the meeting. At latest, 24 hours before FDA advisory committee, meeting papers are circulated. These often focus on risks of a drug and market reacts negatively. This reverses if committee votes positively. We urge clients to buy Sanoff on publication of committee documents. While this strategy is not without risk, we believe the reward more than outweighs this with a a +3 to 5% share price reaction possible. Compared to this time last year, the data on Acomplia is stronger. This is because the drug has launched successfully in Europe and because data in the diabetes population (published last Dec) called SERENADE was positive. Meeting papers to be published next week may have a negative tone but we'd use that as an opportunity to pick up stock.
		100	Last	Report	Date and	' Title	(2)	Morning meeting summary
						Analyst ¹	(1)	. Dresdner Kleinwort

Case 1:0#-ev-19279-GBD-FM

Analysts' Comments About Rimonabant's Prospects for Approval Before and After the June 11, 2007 Release of the FDA Brief Sanofi-Aventis Exhibit 14

Following the Release of FDA Brief:

Did Analyst

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s Non-Approval	AdCom	Recomendation	Was	a Possibility? Recommendation? Implied!	(8)	Yes	
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	6/11 or 6/12 Report Following the Release of 6/11 FDA Brief			Quote	(5)	 ▼ The FDA has posted its questions to the advisory expert panel who will review the risk/benefit profile of Rimonabant (Acomplia in the EU, Zimulti in the USA) on 13 June, as well as briefing documents. ▶ In light of documents published today, we have attempted to answer these questions, putting ourselves in the shoes of an advisory panel member. ▶ To summarise, we believe that psychiatric/neurological side effects seen with Acomplia 20mg are "clinically important" (question 1b), including an increase in suicidality which appears no higher than SSRI antidepressants. However, we still believe the balance of benefits versus risks favours Acomplia (question 3a). ▶ We still anticipate a requirement for a blackbox warning on psychiatric and neurological side effects excluding patients with a history of depression (40% of the cases of suicidality) together with tight risk-management and a pharmacovigilance programme. ▼ The debate is likely to be heated on Wednesday, especially following the Avandia issue. The 14-member panel vote in the evening of 13 June may be close, which would extend the market's nervousness until 26 July. ► As a reminder, the panel meeting will take place on 13 June from 8.00am to 17.00pm local time (14.00pm to 1.00am CET). The FDA then has untill 26 July to decide upon the drug's fate (approval, non approval or more data required). If positive, SAN expects to launch the drug in Q4 07. 	
	6/11 or 6	Report	Date and	Title	(4)	6/12/07 Acomplia: in the shoes of an FDA panel member	
	Last Report Prior to the Release of 6/11 FDA Brief ²			Quote	(3)	be the review of Acomplia by a panel of FDA experts on 13 June, who we believe will recommend the drug's approval with a black-box warning on CNS side effects. Until then, the stock is likely to stagnate due to the uncertainties involved with the FDA's decision on Lovenox's replicability (timing uncertain, we assume a favourable outcome) and judge Stein's decision in the Plavix trial (favourable decision expected but unlikely before H2 07).	
	Last Re	Report	Date and	Title	(2)	Solid Q1 results on tight cost management	
			,	Analyst 1	(1)	4. Exane BNP 5/3/07 Paribas Solid (results cost manage manage)	

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Exhibit 14
Sanofi-Aventis
Analysts' Comments About Rimonabant's Prospects for Approval
Before and After the June 11, 2007 Release of the FDA Brief

ase	e 1	L:O	What Was The	Most Like	Outcome	that Analy <mark>so</mark>	27/pieS	Implied (C	GB (01)	D-FM Document 188-1 Filed 04/30/12 Page 62 of 1
se of FDA Brief:		Did Analyst	Predict W	>50% Non-	Approval or	Negative	AdCom	commendation?	(6)	No No
Following the Release of FDA Brief:	Did Analyst	Believe that	Non-Approval	or a Negative	AdCom	Recomendation	Was	a Possibility? Recommendation? Implied	(8)	Yes
Fo			Did Analyst's	Approval	View	Become	Less	Favorable?	(7)	Unclear
	Prior to FDA	Brief, Did	Analyst Note the Did Analyst's Non-Approval	Possibility of	Non-Approval	or a Negative	AdCom	Recommendation? Favorable?	(9)	No No
					6/11 or 6/12 Report Following the Release of 6/11 FDA Brief		þ	Quote	(5)	Suspense will persist to the end. The verdict will be given on Wednesday evening. in a difficult context after the media hype on the side effects of Avandia (GSK), the verdict could go either way in our view, although logically the product should be approved. In any case, only a very clear decision with a strong majority of experts would guarantee approval from the FDA on 26 July. Valuation: The share should react sharply on mnouncement of the very low verict, given the product's symbolic position in the group's pipeline. In addition to the impact of the announcement, we think that the very low valuation for sanoffaventis is consistent with the possibility of the loss of Plavix and Acomplia US.
					6/11 0	Report	Date and	Title	(4)	6/11/07 Robust product pipeline raises outlook in wake of emerging generic competition 6/12/07 Suspense continues on rimonabant
					Last Report Prior to the Release of 6/11 FDA Brief ²			Quote	(3)	Recent new launches, like Acomplia and Apidra, are also expected to boost the company's revenues considerably going forward. The materialisation of potential for some molecules will only fully emerge, in our view, after the decision from the FDA consultative committee on Acomplia.
					Last Ro	Report	Date and	Title	(2)	Company News Alert 4/25/07 SANOFI- AVENTIS Encouraging results for VEGF and Trovax at ASCO 6/1/07 Eyes on Japan
								Analyst 1	(1)	5. IIR Group 6. IXIS

Exhibit 14

Sanofi-Aventis

Analysts' Comments About Rimonabant's Prospects for Approval

Before and After the June 11, 2007 Release of the FDA Brief

Case 1

What Was Take Most Like Outcome Said Said (10)	Defense Solon Document 188-1 File	egl 04/30/12 Page 63 of 141
Howing the Release of FDA Brief: Did Analyst Believe that Did Analyst Ora Negative >50% Non- Most Liken AdCom Approval or Outcome Recomendation Negative that Analyst Was AdCom Said/ A Possibility? Recommendation? Implied So	N _O	Z
Following the Release of FDA Brief: Did Analyst Believe that Did Analyst s Non-Approval Predict W or a Negative >50% Non- AdCom Approval or Recomendation Negative t Was AdCom a Possibility? Recommendation?	Yes	Yes
E Did Analyst's Approval View Become Less (7)	ON.	Unclear
Prior to FDA Did Analyst Brief, Did Analyst's Non-Approval Possibility of Approval or a Negative Non-Approval View AdCom or a Negative Become Recomendation AdCom Less Was Recommendation? Favorable? (6) (7) (8)	Yes	°Z
6/11 or 6/12 Report Following the Release of 6/11 FDA Brief eport te and Quote (4) (5)	Incrased "suicidality" looks to be the major FDA concem. On the positive side, the FDA does conclude that Zimulti gives "statistically and clinically meaningful weight loss", but must judge the risk-benefit with respect to the increased suicidality risk. It's a very close call. Risks to our rating 2) We forecast US approval for Acomplia in H2 2007. US approval cannot be guaranteed and could be subject to further delay. Delays to Acomplia in the US would be damaging to the share price.	Yesterday evening, the FDA published on its website the briefing document for Acomplia that will be presented to the advisory committee experts on 13 June After reading this document, as well as the accompanying letter, we think it is very difficult to tell what conclusion the advisory committee will draw The experts are bound to focus on the risk of suicide that seems to be linked to taking Acomplia. The FDA does not hide the fact that it is concerned about the consequences that taking the product has on central cannabinoid receptors In the past, we have often been led astray by the contents of a briefing document and the alarming tone of the expert in charge of summarising a compound's side effects. We will wait to see the final vote of the 14 experts tomorrow.
6/11 or 6 Report Date and Title (4)	6/11/07 FDA focus on Zimulti swicidality risk - ALERT	6/12/07 3 SANOFI- AVENTIS - Acomplia/Zim ulti: a 'neurological' dossier that is a first for an obesity treatment - 12th June, 2007.
Last Report <u>Prior</u> to the Release of 6/11 FDA Brief ² ort and e (3)	We forecast US approval for Acomplia in H2 2007. Clinical data so far show Acomplia to be safe and effective and the product is now approved in Europe. Nevertheless the US approval cannot be guaranteed and non-approval of Acomplia in the US would be damaging to the share price.	The NDA for Acomplia in the US, delayed on two separate occasions. Although the PDUFA date has been set for 27 July, the advisory committee will issue their opinion on 13 June, which is now the key date for the product's immediate future in the US. The key dates are still 13 June when the FDA experts will announce their opinion of Acomplia, when the judge in charge of the Plavix case in the US announces his decision, and an R&D update later in the year.
Last Re Report Date and Title (2)	5/4/07 Sanofi-Aventis : Guidance increased but not enough	5/30/07 FDA approves Xyzal 5/3/07 Time to reflect 5/3/07 Although Q1 results blew hot and cold, the group was in a position to raise its guidance
Analyst ¹ (1)	7. JP Morgan	8. Raymond James Euro Equities

ase of FDA Brief:

Did Analyst

Predict What Was Take Following the Release of FDA Brief:

Sanofi-Aventis Exhibit 14

Analysts' Comments About Rimonabant's Prospects for Approval Before and After the June 11, 2007 Release of the FDA Brief

Prior to FDA Did Analyst

Brief, Did Believe that

Analyst Note the Did Analyst's Non-Approval

Classes Comments to eagerly awaiting reassurance on Plavix in the US, Acomplia approval in the US and the late-street couple of months. Committee of experts will meet be a concern, the PDA and any potent to be a concern, the PDA and any potent to be a concern, the PDA and any potent to be a concern, the PDA and any potent to be a concern, the PDA and any potent to be a concern, the PDA and any potent to be a concern, the PDA and any potent and the PDA does not question on the PDA website of the documents related to committee. Committee.	(5) Among the potential catalysts, Plavix's US patent should be upheld, Acomplia should be approved in the US and a number of Phase III trial results are to be announced shortly at scientific meetings.	or a Negative	Become	Recomendation		L
Title (4) (5/12/07 FDA Teleased earlier, highlight CNS side-effects side-effects The FDA has specifically three questions for its Advisory Committee	(5) (5) thial catalysts, Plavix's US patent 4, Acomplia should be approved in mber of Phase III trial results are to tortly at scientific meetings.			TACOMORIA MARCON	Negative	that Analys
Title (4) (4) (5/12/07 FDA decerrier, inghlight CNS side-effects side-effects 6/12/07 The FDA has specifically n three questions for its Advisory Committee	Quote (5) third catalysts, Plavix's US patent J, Acomplia should be approved in mber of Phase III trial results are to tortly at scientific meetings.	AdCom	Fess	Was	AdCom	Said/ Said/
(4) (6/12/07 FDA documents released earlier, highlight CNS side-effects side-effects (6/12/07 The FDA has specifically n three questions for its Advisory Committee	(5) Intial catalysts, Plavix's US patent J, Acomplia should be approved in mber of Phase III trial results are to tortly at scientific meetings.	Recommendation? Favorable?	Favorable?	a Possibility? R	a Possibility? Recommendation? Implied!	Implied !
6/12/07 FDA ne documents released earlier, highlight CNS side-effects side-effects nh free questions for its Advisory Committee	ntial catalysts, Plavix's US patent I, Acomplia should be approved in mber of Phase III trial results are to tortly at scientific meetings.	(9)	(2)	(8)	6)	GB ê
6/12/07 The FDA has specifically on three questions for its Advisory Committee	We ultimately expect the experts to recommend rimonabant for approval, aboit in very specific populations with the highest risk, like obese/overweight patients with type 2 diabetes. We also expect the experts to vote in favour of a serious warning about the CNS risks (black box on suicidal risk?).	Yes	°Z	°Z	°Z	D-FM Document 188-1 Filed (January Physical Street Stree
The FDA has specifically on three questions for its Advisory Committee	The FDA does not question at all the efficacy of the)4/
specifically on three questions for its Advisory Committee	product but how side-effects could be managed in					30,
for its Advisory Committee	practice. The FDA explicitly recognizes that the safety database for rimonabant is large and growing					/12
Committee	and that the company has initiated large clinical trials to evaluate the effect in reducing cardiovascular					F
	morbidity (e.g. CRESCENDO, which has already					aç
PI	recruited 8,000 patients on the 17,000 planned). We think the panel will vote in favour of a very specific indication (perhaps more restrictive, to only type 2 diabetic patients) WITH a warning on psychiatric side-effects.					ge 64 of 141

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Exhibit 14
Sanofi-Aventis
Analysts' Comments About Rimonabant's Prospects for Approval
Before and After the June 11, 2007 Release of the FDA Brief

Se	9 1	.:C	as Z	ik <mark>a)</mark>	Outcome		27/pieS	ed Q	GB (01)	D-FM Document 188-1 Filed 04/30 Marning Marning Marning Marning Marning Piece 1999
:			What Was File	Most Liker	Outco	that Analy	Sai	? Impli	(1)	Further data request, warning Label C
ise of FDA Brie		Did Analyst	Predict	>50% Non-	Approval or	Negative	AdCom	ecommendation	(6)	ž
Following the Release of FDA Brief:	Did Analyst	Believe that	Non-Approval	or a Negative	AdCom	Recomendation	Was	a Possibility? Recommendation? Implied!	(8)	Yes
FC			Did Analyst's	Approval	View	Become	Less	Favorable?	(7)	°Z
	Prior to FDA	Brief, Did	Analyst Note the Did Analyst's Non-Approval	Possibility of	Non-Approval	or a Negative	AdCom	Recommendation? Favorable?	(9)	Yes
					6/11 or 6/12 Report Following the Release of 6/11 FDA Brief			Quote	(5)	Clear safety concerns; further data may be requested the FDA staff signal rimonabant is associated with higher risk of suicidal ideation, psychological and neurological adverse events and seizures. The FDA could ask for a warning regarding use in patients with history of psychiatric illness will likely ask for further safety data, although this may not prevent (restricted) approval. Clean positive recommendation would be good for the stock. In our view, a positive recommendation by the AdCom for approval in weight loss would be positively received by the market, provided that debate and uncertainty relating to suicide risk is limited. The major drug in development for obesity, Acomplia, received an approvable letter from the FDA and its US launch remains uncertain.
					6/11 or 6/	Report	Date and	Title	(4)	Acomplia AdCom briefing documents set to stimulate debate
					Last Report Prior to the Release of 6/11 FDA Brief 2			Quote	(3)	Stock likely range-bound We believe Sanofi-Aventis will continue to be rangebound until we get more clarity on the following issuesThe Advisory Committee on Acomplia on 13 June. Acomplia, received an approvable letter from the FDA and its US launch remains uncertain.
					Last Ro	Report	Date and	Title	(2)	5/3/07 Q1 review Q1 review 5/3/07 First Read: Sanofi-Aventis "Q1'07 results ahead on cost control" (Neutral 2)
								Analyst 1	(1)	10. UBS

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Analysts' Comments About Rimonabant's Prospects for Approval Before and After the June 11, 2007 Release of the FDA Brief Sanofi-Aventis Exhibit 14

Ca	ase	e 1	L:C	hat Was The	Most Liker	Outcome	that Analy <mark>so</mark>	27/27/27/27	Implied (O	GB (01)	Increased	risk of T	negative	AdCom	vote O	00	uı	m	er	nt	18	38	-1		Fi	ile	d	C)4	/3	0/:	12	F
	se of FDA Brief:		Did Analyst	Predict W	>50% Non-	Approval or	Negative t	AdCom	a Possibility? Recommendation? Implied	(6)	No																						
	Following the Release of FDA Brief:	Did Analyst	Believe that	Non-Approval	or a Negative	AdCom	Recomendation	Was	a Possibility? Re	(8)	Yes																						
	Fo			Did Analyst's	Approval	View	Become	Less	Favorable?	(7)	n.a.																						
		Prior to FDA	Brief, Did	Analyst Note the Did Analyst's Non-Approval	Possibility of	Non-Approval	or a Negative	AdCom	Recommendation? Favorable?	(9)	n.a.																						
Before and After the June 11, 2007 Release of the FDA Brief						6/11 or 6/12 Report Following the Release of 6/11 FDA Brief			Quote	(5)	As outlined in the approvable letter for	Acomplia/Zimulti (rimonabant) from February 2006,	the FDA is concerned about the increased	frequencies of psychiatric adverse events, including	suicidality, an ill-defined constellation of	neurological signs and symptoms, as well as seizures.	Although only two completed suicides during the	clinical trials by participants treated with Acomplia	were reported it appears that according to an analysis	conducted by a team of the University of Columbia	'possible and/or definitive cases of suicidality' did	outnumber the cases for those on placebo vs. active	treatment by three to one. As such we believe that	there is an increase risk that the FDA advisory	committee meeting which is scheduled for	tomorrow, 13 June, is advising against approving	Acomplia in the US.						
sefore and After						6/11 or 6/	Report	Date and	Title	(4)	6/12/07	FDA advisory	committee	briefing	material does	not bode well	for US	approval															
1						Last Report Prior to the Release of 6/11 FDA Brief ²			Quote	(3)																							
						Last Rep	Report	Date and	Title	(2)	6/4/07	Sanofi-Aventis	(SASY.PA) -	ASCO 2007;	some bits and	pieces		5/3/07	Sanofi-Aventis	(SASY.PA) -	Strong Q1	2007 results -	[More]										
									Analyst 1	(1)	11. WestLB	Equity	Markets																				

Notes and Sources:

This exhibit includes uniquely-titled English-language, company-specific, non-technical reports issued during the period that NERA was able to obtain from counsel or purchase from Reuters Knowledge or Thomson Investext.

Total number of "Yes":

List of analysts is limited to those who published a Sanofi report on 6/11/07 or 6/12/07. Excludes Prudential who published a report on 6/12 to state they are terminating coverage of Sanofi Aventis.

³ Reuters lists the date of this report as 6/13/07, however the date listed in the report itself is 6/12/07.

² If the last report prior to the release of the FDA Brief had no relevant rimonabant discussion, the report prior to that one was reviewed.

Sanofi-Aventis Exhibit 15

Change in Analysts' Ratings Prior to and Following the

June 11, 2007 FDA Briefing Document and June 13, 2007 14-0 Advisory Committee Vote

Change in Rating

						From First Rating
		Rating ²		Following	From the Release	Prior to 6/11 to
Analyst Who Published	First Rating			the Release of	of the FDA Brief to	14-0 AdCom Vote,
a Report During 6/11-6/15 ¹	Prior to 6/11/07	6/11/07 - 6/12/07	6/13/07 - 6/15/07	the FDA Brief	14-0 AdCom Vote	14-0 AdCom Vote If No 6/11-6/12 Rating
(1)	(2)	(3)	(4)	(5)	(9)	(7)
				(2) to (3)	(3) to (4)	(2) to (4), it (3) blank
1. ABN AMRO	Hold		Sell			Downgrade
2. Aurel Leven	Hold		Hold			none
3. Bank of America	Buy		Buy			none
4. Bear Stearns	Underperform		Underperform			none
5. Citigroup	Hold (2)	Hold (2)	Hold (2)	none	none	
6. Credit Suisse	Neutral		Neutral			none
7. Deutsche Bank	Buy	Buy	Buy	none	none	
8. Dresdner Kleinwort	Buy	Buy	Buy	none	none	
9. Exane BNP Paribas	Outperform	Outperform	Neutral	none	Downgrade	
10. Goldman Sachs	Buy		Neutral			Downgrade
11. HSBC Global Research	Overweight		Neutral			Downgrade
12. IIR Group	Buy	Buy	Hold	none	Downgrade	
13. ING	Hold		Hold			none
14. IXIS	Add	Add	Add	none	none	
15. JP Morgan	Overweight	Overweight	Neutral	none	Downgrade	
16. Jyske Bank	Accumulate		Sell			Downgrade
17. Lehman Brothers	2-Equal weight		2-Equal weight			none
18. Oppenheim	Buy		Buy			none
19. Merrill Lynch	Buy		Neutral			Downgrade
20. Morgan Stanley	Overweight		Overweight			none
21. Raymond James Euro Equities	Fair Value	Fair Value	Fair Value	none	none	
22. Societe Generale	Buy	Buy	Hold	none	Downgrade	
23. UBS Investment Research	Neutral 2	Neutral 2	ю	none		
24. WestLB Equity Markets	Hold	Hold	Hold	none	none	
Analysts with a Downgrade in Rating	ing					
Number Percent				0 of 11 0%	4 of 10 40%	5 of 13 38%

Page 1 of 2

Exhibit 15

Sanofi-Aventis

Change in Analysts' Ratings Prior to and Following the

June 11, 2007 FDA Briefing Document and June 13, 2007 14-0 Advisory Committee Vote

Notes and Sources:

purchase from Reuters Knowledge or Thomson Investext. If there are more than one report by the same analyst in the exhibit's date range, the report shown is the one with the This exhibit includes uniquely-titled English-language, company-specific, non-technical reports issued during the period that NERA was able to obtain from counsel or change in rating (if the rating is not the same across reports).

¹ List of analysts is limited to those who published a report during 6/11-6/15. Excludes Prudential who published a report on 6/12 to state they are terminating coverage of Sanofi Aventis.

² For each analyst, where available, the first report prior to the public release of the FDA Briefing documents was reviewed as well as any reports published in the days leading up to and following the Advisory Committee 14-0 Vote on the non-approval of rimonabant. If a particular analyst report provided the previous rating, this was noted, and the prior period report was not reviewed.

³ Effective 6/12/07, UBS ceased coverage of Sanofi Aventis due to reallocation of resources.

Exhibit 16 Sanofi-Aventis Analyst Report Discussion of the June 13, 2007 FDA Advisory Panel Vote June 13, 2007 through June 15, 2007

	Quote	(4)	. We now see no prospect of approval for rimonabant (obesity) in the US and potential for adverse labelling in Europe. The lack of this major
	Title	(3)	Serious adverse event
Report	Analyst		ABN-AMRO
	Date	(1)	. 6/14/07
			1.

adverse event	We now see no prospect of approval for rimonabant (obesity) in the US and potential for adverse labelling in Europe. The lack of this major growth driver for revenues leaves the company unable to overcome major generic erosion 2007-12F. Sell.
	Advisory committee negative with implications for European label An FDA advisory panel unanimously voted against approval of rimonabant in the US on 13 June 2007. This followed an FDA presentation described
	by one panellist as a 'spectacular analysis', which raised serious concerns about the safety of rimonabant. The 14-0 vote against the drug
	highlighted risks of psychiatric and neurological adverse events, which not only militates against approval of the drug in the US but could,
	we believe, also lead to label changes and even regulatory action in Europe.

Advisory Committee outcome was crushingly negative

The FDA advisory panel, which met to consider the use of sanoff-aventis' rimonabant in treating obesity, voted 14-0 against both questions; does the currently available data sufficiently characterise the safety profile of the drug; and does the drug have a favourable risk-benefit ratio?

presentation focused very much on the pre-clinical toxicity data, highlighting the very similar doses between those causing serious adverse events such as convulsions in a range of animals, including monkeys, and the dose applied for use in humans. These concerns were increased, in our view, by The unanimous negative votes from the panel appeared to be based on very material concerns over the safety of the drug. The FDA the high level of psychiatric adverse events reported to the European authorities compared to other weight-loss drugs. The overall view of the committee, we believe, can be summed up in the words of Dr J Hirsch, Professor at the Rockefeller University, New York. He was glad that the drug was available for research, acknowledged the high level of work undertaken by sanofi-aventis in developing the drug so far but concluded that the data suggests that 'in no way' should this drug be approved for use... In our view, the very recent post-marketing surveillance data that was presented to the panel on the experience of the drug in Europe and the incidence Medicines Agency (EMEA) has been reported (AFX News 14/07/07) to have said that it will review any new information on rimonabant. The drug's of adverse events with rimonabant in Europe raises the risk of further regulatory action in those markets where the drug is available. The European label already carries a warning of psychiatric side-effects in Europe (source: EMEA).

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Exhibit 16 Sanofi-Aventis

Analyst Report Discussion of the June 13, 2007 FDA Advisory Panel Vote

June 13, 2007 through June 15, 2007

L. U	"	CV-	10213	ו-טטט-ו	W Docume	2111 TOO-T	illeu	04/30/	12	ray
	Quote	(4)	We warned investors about the risk of disappointment from the American FDA advisory panel review of Zimulti (rimonabant, abdominal obesity), which took the form yesterday of a unanimous (14 votes to 0) rejection by the FDA experts of marketing the product in the United States.	This rejection is based on increased psychiatric risk, in the form of depression and suicidal thoughts. The experts said that additional safety data were required, and suggested that the FDA wait for the results of additional clinical trials available in 2010. The decision of the FDA is due on July 26. It generally follows the opinion of its experts.	We believe that the only chance for Zimulti to access the US market is the CRESCENDO trial, which studies the morbi-mortality rate of the drug. If results are positive, the risk/benefit ratio of the product could be favourable and prompt a change of view by the American regulator. There is however a real problem, as the results are expected in 2010 and CRESCENDO has already reported two attempted suicides (one a woman of 60 and one a man of 56), and one case of suicidal thoughts (woman of 64), all three being administered rimonabant 20 mg.	In the event of positive outcome for CRESCENDO, Zimulti could be marketed in the United States from 2011, in an environment which is substantially more competitive, with the likely coming to market of CP 945 598 from Pfizer, of taranabant from Merck&Co and even SLV 319 from Bristol-Myers Squibb/Solvay. We now expect the American launch of Zimulti in 2011, although we believe that marketing in Europe is likely to continue but with a more restricted label (1/ the European regulator gave its decision last year on the basis of the same clinical data, 2/ FDA is very	much under the fire of its critics, since the Vioxx affair, and more particularly with Avandia at this time).	Despite the setback on Acomplia in the US (which we are removing from our estimates), we are maintaining our buy rating on SNY shares. Advisory Committee Outcome: Acomplia Appears Dead In US.	After a one-sided discussion of risks associated with Acomplia, the FDA panel voted that safety signals (psychiatric and neurological) were not sufficiently characterized to approve the product.	
	Title	(3)	Sanofi-Aventis: Icy blast					More To The Pipeline Than Acomplia:	Maintaining Buy Rating	
Report	Analyst	(2)	Aurel Leven					Bank of America		
	Date	(1)	6/14/07					6/13/07		
1			2.					3.		

Exhibit 16

Sanofi-Aventis

Analyst Report Discussion of the June 13, 2007 FDA Advisory Panel Vote June 13, 2007 through June 15, 2007

	Quote (4)	Unanimous vote against approval: The Endocrine and Metabolic Drugs Advisory Committee Panel has voted unanimously (14 to 0) against approving Zimulti for weight loss in obese patients due to insufficient data to characterise its profile. Safety remains a big concern: In particular, the panel members were concerned about the increased suicidal ideation (including completed suicides), higher depression, seizure and MS rates observed in the Zimulti 20mg treated patients vs placebo, which warrant further investigation. The panel members were also concerned about the cardiovascular effects of the drug (principally why LDL and blood pressure does not decline with therapy).	the body language of panel members and the huge majority in favour of rejection, it is highly likely the FDA will not approve the drug. For prudence, we are removing US sales for Zimulti from our Sanofi model	 ▶ Food & Drug Administration (FDA) advisory panel unanimously reject Acomplia as unsafe — As we have maintained since pre PDUFA, February 2006 report, "Mission Acomplia I" The FDA advisory committee voted unanimously 14-0 that there is insufficient data to prove Zimulti is safe, and voted 14-0 against allowing U.S. approval as a weight loss drug. The use as a diabetic drug was also ruled out at the start of the panel. ▶ Double suicidality risk an underestimate — As previously stated, predictable neuropsychiatric side-effects such as suicide risk considered an underestimate as psychiatric withdrawn patients were not followed up and depressed people excluded (30% prevalence). Moreover, the original NDA had a single suicidality case, but upon FDA requested reexamination, the original data had 54 cases. ➤ No U.S. Zimulti until 2012.—With the next trial ADAGIO not a regulatory endpoint, CRESCENDO the 17,000 patient, 5-year mortality trial will answer the risk-benefit concern. With 6,000 recruited in 18 months, we see difficulty reaching 17,000 & a resubmitted NDA until 2012, now that 4 cases of Zimulti associated suicide are publicly known. Suicide fears & competitors may pare any eventual U.S. sales. ➤ European sales at risk — The European regulators will receive the full safety data collected by the FDA, which may put EU approval at risk, being based upon a single "unclear" suicide was a non-overweight European man with a BMI of just 22. With the key variable, Acomplia, being rejected by the FDA advisory panel removes any near-term U.S. sales potential until 2012
	11fte (3)	Zimulti Gets Thumbs Down From the FDA Panel: Sell		Mission Unaccomplished
Report	Analyst (2)	Bear Steams		Citigroup
	Date (1)	4. 6/14/07		5. 6/14/07

Analyst Report Discussion of the June 13, 2007 FDA Advisory Panel Vote June 13, 2007 through June 15, 2007	Ouote		The FDA Advisory Committee discussions were consonant with the concerns we have raised with investors over the last three years over Consonability of a recommendation for approval of Zimulti should now see consensus move to an assumption that the drug will be unlikely to receive US approval by the July 26th PDUFA date.	Following the FDA advisory committee meeting, we are revising our Acomplia forecasts – removing US revenues from our model and lowering our accounts. The state of the FDA advisory committee meeting, we are revising our Acomplia forecasts – removing US revenues from our model and lowering our accounts. The state of the FDA advisory committee meeting, we are revising our Acomplia forecasts – removing US revenues from our model and lowering our Acomplia forecasts – removing US revenues.	Removing US Zimulti forecasts reduces 2008-12E EPS by 5-6% With the potential for an Acomplia EU recall mitigated by adaptions to scale following the FDA panel's negative stance on Zimulti in the US, we project a potential net 8% downside to SASY's valuation.	FDA panel reject approval of Zimulti based on safety concerns The FDA Endocrinology and Metabolic Drugs Advisory Committee voted unanimously (14:0) to reject the approval of Zimulti. Whilst the panel accepted that Zimulti provided a significant weight loss benefit, it had a number of concerns surrounding safety. Whilst the panel concurred with the FDA's analysis of the magnitude of the increased risk of suicidality (HR 1.9), psychiatric events (HR 1.9) and serious neurological events (HR 1.7) shown by Zimulti 20mg relative to placebo, it felt that the high discontinuation rate likely under-estimated these risks.	In addition an EMEA post-marketing database highlighted 54% of Acomplia AEs were psychiatric cases (21% for Meridia; 8% for Xenical) = and that 27 cases of suicide ideation had been reported since launch in 2006 versus just 15 cases with Meridia (1999 launch) and 14 cases O with Xenical (1998 launch).	•	screened for a lack of depression/epilepsy fell on deaf ears as the risk of CNS adverse events such as depression was still 2-fold higher in the AZimulti arm in patients without a history of depression.	The lack of detailed knowledge surrounding Zimulti's antagonism of the endocannabinoid system, together with the dose and time dependency of adverse events in animal studies and mechanistic hypotheses engendered further caution. Finally the EMEA post-marketing database highlighted 54% by Acomplia AEs were psychiatric cases (21% for Meridia; 8% for Xenical) and that 27 cases of suicide ideation had been reported since launch in 2006 vs just 15 cases with Meridia (1999 launch) and 14 cases with Xenical (1998 launch), although the rigorous EU surveillance program for Acomplia and the lack of a recent post-marketing update for Meridia and Xenical likely exaggerates this trend.
	Title	(3)	US Zimulti out of the model		Approval of Zimulti for obesity rejected by FDA	panel				
	Report Analyst	(2)	Credit Suisse		Deutsche Bank					
	Date	(1)	6. 6/14/07		7. 6/14/07					

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The significant clinical benefit of Acomplia highlighted by the FDA panel was wiped out by the requirement for a more precise understanding of a Acomplia's psychiatric side effects, in particular what happened to patients who dropped out of the trial due to adverse events (and notably depression). A number of panellists also asked for data beyond two years of treatment (which was not required by the FDA) as well as better pre-specified than the trials design were pre-agreed with the FDA)... Case 1:07-cv-L0279-GBD-FM Document 188-1 Filed 04/30/12 deny full approval at the end of July. However, we still expect Plavix litigation to go in favour of Sanoff and this should have a plus 5 to 10% through the FDA and the delay. The FDA committee has not followed Europe, which is perhaps surprising to us. But without going into too Our advice is that the Bull call is not over in Sanofi although we've taken a hit. If and yes it is a big if, you can look through this, then the risk/reward pre-specified characterisation of side effects. This means that SAN is unlikely to be in a position to address the panel issues before the outcome of Pending the outcome of the CRESCENDO trial, we now include in our model the worst-case scenario for Acomplia which includes no sales in initial launch investment costs in the US will not bear fruit. And this is likely to affect near term margin. Looking to the future, FDA are likely to The panel's concerns notably included the need for patient follow-up longer than the two years so far required by the FDA as well as better Our bet on Acomplia has not worked out, FDA advisory committee voted 14 – 0 against approval at this time as it considered more safety data was It looks like we will have to wait for CRESCENDO study data in 2010, which looks at mortality and outcome data as well as safety. This suggests We are cutting back our Acomplia sales forecast by c. 60% in 2010 to EUR800m, reflecting higher risk that this drug will never make it decision in the stock is still skewed positively from this level. So, we're still buyers on valuation and the Plavix call but will understand if some The FDA's advisory committee was unanimous that the currently available data insufficiently characterizes the safety profile of rimonabant required. No dispute over efficacy. If investors can hang on then the Plavix bet is still very much intact. We cut our target price to EUR80. he 17,000 patient CRESCENDO trial in 2010-2011 and may also have to amend existing phase IV trials and/or initiating new ones.. Sanofi-Aventis is unlikely to be in a position to answer the FDA panel's questions before 2010 investors give up. We advise to hang on for the next 6 months. BUY new tp 80. Ouote 4 (Acomplia/Zimulti) and hence voted against approving the drug at this stage. much detail; efficacy is not in question but safety data is just unclear. We now factor our worst-case scenario on Acomplia in SAN's model the US and a much more limited ramp up for the product in Europe. FDA advisory committee requires more safety data for Acomplia June 13, 2007 through June 15, 2007 effect on the stock. Rating downgrade to Neutral - FDA panel meeting summary curbs Acomplia's (Buy) - Morning Sanofi-Aventis Title 3 prospects Report Analyst Exane BNP Kleinwort 3 Dresdner Paribas

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L.U	, , ,	-CV-	10279-GE	D-FIM DO	ocume	188-1	. Filed 04/30/3	اک Pay	2 /4 01 141
	Quote	(4)	News An FDA Advisory Committee yesterday (13 June) voted 14-0 against approving Zimulti/Acomplia (obesity) on the basis of the product's safety profile, i.e. that there were insufficient data to characterize its profile and on the available data that the risk-benefit profile was not favourable. FDA will give its verdict on the product's approvability by 26 July.	Analysis Whilst FDA is not obliged to follow the panel's negative recommendation we believe it is unlikely that it will approve this product in the near term. We note the FDA's "very strong belief of a causal link" between suicide risk and Acomplia use and the Advisory Committee's overwhelmingly negative comments towards the product's safety profile. We believe US approval now appears unlikely at least until the CDESCENDO cardiogeorge outcomes study resource in 2010. Our content model includes Eurobay Girmulti's capacity of several in 2011.	S0% of incremental sales growth 2006 – 2011e).	We have removed US Acomplia from our earnings model – though US approval remains a remote possibility, it will not come this decade in our view and the market will take a sceptical view of its outlook. Investors will now focus on a limited pipeline ex-Acomplia and a very challenging patent profile, such that the prospect of M&A will likely come in to focus in our view.	Whilst US approval remains possible in the coming years, we believe that the product's safety profile as discussed by the Advisory Committee is currently insufficiently determined and will require additional long-term data. It is unclear if the ongoing CRESCENDO cardiovascular outcome study (reports 2010) will provide sufficient information and it is possible that the FDA might require an additional study to address its concerns. FDA's stance will not be formalized until around the July 26 PDUFA date; we may not receive any detailed comment from sanofi-aventis until then.	The FDA Adcom review of Acomplia exposes the flaws in a pioneering drug development strategy. Investors will now question the value of new drugs until regulatory approval. We remain optimistic for the near term pipeline, but accept that investor sentiment will limit the positive share price impact.	The risk of novel drugs development in now real The FDA advisory committee (Adcom) voted unanimously not to recommend approval of Acomplia. The main concern was focused around the central nervous system (CNS) side effects associated with Acomplia - the panel felt the risks of Acomplia could not be managed once the drug was made broadly available in the US. Further the panel was concerned that Sanofi had not provided sufficient long-term data for what would be a widely used long term therapy.
	Title	(3)	First Take: Advisory committee vote 14-0 against Zimulti/Acomplia			Negative opinion for Acomplia in FDAC; downgrade to Neutral		Adcom torpedoes drug development reputation	
Report	Analyst	(2)	Goldman Sachs			Goldman Sachs		HSBC Global Research	
	Date	(1)	6/14/07			6/14/07		6/14/07	
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Quote	(4)	FDA advisory committee says NO The FDA advisory committee voted unanimously not to approve Acomplia as an adjunct to diet and exercise for obesity management in patients with a body mass index > 30kg/m2, or a body mass index > 27kg/m2 if accompanied by at least one cardiovascular risk factor.	As expected the committee focused its discussions on the central nervous system side effects associated with Acomplia. These include depression, anxiety, mood disorders and unexpectedly suicide ideation and seizures. Sanofi for its part was open with the committee regarding the span of its clinical data package (covering over 15,000 patients), but the committee was unimpressed preferring to focus on the up to 50% annual drop out rates in the pivotal studies and the fact that only 441 patients took the drug for two years. This was major concern for the committee since Acomplia would be a chronic life time therapy.	The panel was also concerned that the neurological (seizures) and psychiatric (depression, anxiety and suicidal ideation) side effects were in a highly screened population that does not represent the broader US population which includes Hispanics, African Americans and males who were not properly represented in the pivotal studies. The panel also criticised the collection of CNS adverse event data and the follow up of patients who had withdrawn due to side effects (up to 50% per annum) in the pivotal studies. This was important as far as the committee was concerned because it left the full impact of the CNS side effects un-quantified. Finally the committee asked why Sanofi had not been more thorough in monitoring the CNS side effects since it knew all along that this was a drug which acted on the brain.	Sanofi responded with an extensive risk management program which met the usual response from FDA and its committee to chronic drugs targeted at large (millions) patient populations – you cannot control the beast once it is out the cage. In conclusion Sanofi has undertaken the development of a unique new chemical entity in Acomplia, defined a whole area of science (CB1 sreceptors in the periphery), but failed to fully accept the importance of the known broad central nervous system role for the cannabinoid receptor and Acomplia. In our view this global criticism of the execution of the Acomplia development program is important.	Failure to secure US approval is a major setback for Sanofi-Aventis S.A (Sanofi-Aventis), since Acomplia (known as Zimulti in US) was expected to be a multi-billion dollar drug. Furthermore, the emergence of generic competition for Lovenox and Plavix remain a cause for concern. However, the company's rich product pipeline and potential product launches coupled with initiatives to strengthen its vaccines business are likely to aid growth, going forward. As a result, we temporarily moderate the Sanofi-Aventis common stock from a BUY to a HOLD. We are temporarily moderating Sanofi-Aventis' ADR from a BUY to a HOLD on account of the failure to approve Acomplia in the US. We continue to expect a significant positive currency impact on the ADR in the medium to long term.
	(3)					Company news alert regarding rejection of US approval for Acomplia
Report Analyst	(2)					IIR Group
Date	Ξ					6/14/07
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	Quote	(4)	On 13 June 2007, the US Food and Drug Administration (FDA) Endocrinologic and Metabolic Drugs Advisory Committee voted against the US approval of Acomplia, Sanofi-Aventis' drug for treating obesity. The drug was unanimously voted against by the advisory committee citing inadequate safety data. Acomplia was expected to be a multi-billion dollar drug. The drug generated US\$20 mn sales in 1Q 07. Acomplia (Known as Zimulti in the US) is already approved and marketed in 37 and 18 countries, respectively. Acomplia is a new type of drug to cure obesity that helps obese people reduce weight by blocking the patient's food craving signals in the brain. However, the advisory committee reported that patients using Acomplia were likely to have mental problems such as depression and anxiety leading to increased suicidal thoughts. The advisory committee's decision creates ambiguity for the US approval for Acomplia, for which the final FDA decision is expected by 26 July 2007. The FDA usually follows the committee's recommendations regarding the drug approvals.	The advisory committee's decision creates uncertainty over the final FDA approval for Acomplia. A negative decision by the FDA for Acomplia's approval will be a major setback to Sanofi-Aventis's revenues from the drug, since Acomplia was expected to be a multi-billion blockbuster drug going forward Furthermore, the rejection of Acomplia's US approval coupled with increasing generic competition to a number of major drugs of the company may hamper its top-line going forward.	Failure to secure US approval is a major setback for Sanofi-Aventis S.A (Sanofi-Aventis), since Acomplia (known as Zimulti in US) was expected to be a multi-billion dollar drug. Furthermore, the emergence of generic competition for Lovenox and Plavix remain a cause for concern. However, the company's rich product pipeline and potential product launches coupled with initiatives to strengthen its vaccines business are likely to aid growth, going forward. As a result, we temporarily moderate the Sanofi-Aventis common stock from a BUY to a HOLD.	Following a negative opinion from an FDA advisory committee, Acomplia's US approval prospects now look negligible. We have therefore revised down our forecasts accordingly and set a new target price of €69. HOLD Why the surprise decision? Why the surprise decision? Why the committee members agreed that efficacy of Acomplia had been demonstrated, they did not believe safety had been. Concerns centred on the potential of Acomplia to cause psychiatric as well as neurological side effects. In particular the committee focused on its potential to cause psychiatric events such as suicidal thoughts and depression and neurological events such as seizures. The FDA highlighted in its presentation psychiatric events such as suicidal thoughts and depression and neurological events such as seizures. The FDA highlighted in its presentation that these were probably the direct result of the drug's mechanism of action, ie, inhibition of CB1 antagonist including those present in the brain. Despite the fact that actual suicide attempts in the Acomplia trials were isolated incidents and the relatively benign post marketing experience in the c.100,000 patients in Europe who had taken the drug, the advisory committee members still felt the safety of Acomplia had not been well characterised. The committee also felt the c.5% of weight-loss benefit of the drug was modest and disappointing.
	Title	(3)			Rejection of US approval for Acomplia	Acomplia Woes
Report	Analyst	(2)			IIR Group	ING
	Date	Ξ			6/14/07	6/14/07
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	Quote	(4)	News: The FDA advisory committee voted 12 to 0 against recommending rimonabant (Acomplia) for approval. The committee cited the risk of adverse neurological effects, which have been largely re-analysed by the FDA (and notably the suicidal urges that were twice as prominent in the Acomplia group as in the control group).	Implications: The FDA is to issue its verdict on 26 July and it is bound to follow the committee's recommendation. Negotiations will then take place between sanofiaventis and the FDA concerning the additional clinical trials that could be supplied to the regulator, but we now see very little hope of the product eventually being approved in the US	The FDA's decision could also affect the product's sales momentum in Europe, bearing in mind that the European authorities did not consider these suicidal urges to be an important element in their decision to approve the product. Acomplia's failure to access the US market removes a major source of future growth momentum. Our five-year top-line growth forecast therefore falls from 4.2% to 3.6% a year.	The market is likely to react very negatively today. The product is highly emblematic and the failure will maintain a low level of pipeline credibilityThe announcement on Acomplia, underlines the sometimes -random nature of the FDA's decisions (reflecting the political context), and could also take a toll on the sector and delay its return to favour.	Following yesterday's slide, sanofi-aventis's valuation has now reached a floor for the sector (9.9x 2009 prospective earnings), but it should appreciate if the Plavix trial verdict is positive (anticipated between now and October 2007). Given Acomplia's failure in the US and the lack of growth drivers for post-2012, the group could be prompted into a strategic review in the near future. This process could be accelerated by Total's withdrawal or the sudden arrival of a new shareholder along the lines of Bernard Amault's entry into Carrefour.	Following the negative outcome of the FDA Advisory committee meeting we have removed US Zimulti from our Sanofi-Aventis model. Although we accept the ongoing clinical study program may ultimately result in US approval at some time in the future, we believe the current FDA endocrinology team has no desire to become responsible for Zimulti on their watch.	Following the news of the non-approval of Acomplia for the US market, we remove Sanoff-Aventis from our equity-research universe with a SELL recommendation. This is due to the following: 1. We see no significant price triggers in the short term; 2. We only foresee limited possibilities of EPS upgrades in 2007; 3. the share enjoys very moderate customer interest at the moment
	Title	(3)	Acomplia Knocked Back in the USA				What strategic alternatives after the failure of Acomplia?	Negative Zimulti vote; downgrading to Neutral	We remove Sanofi- Aventis from our equity-research universe
Report	Analyst	(2)	IXIS				IXIS	JP Morgan	Jyske Bank
	Date	(1)	6/14/07				6/15/07	6/14/07	6/14/07
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Quote (4)	Vesterday an FDA Advisory Committee voted unanimously (14:0) against approval of Zimulti/Acomplia for the treatment of obesity. The overriding concern was CNS safety, namely suicidality, psychiatric events, neurological symptoms and seizures. Committee members tended to feel that the quality of the safety data was not sufficient to draw firm conclusions and the signals were too worrisome to allow approval at this stage. There was clear recognition that many patients could benefit from the drug and the Committee were overall complimentary about all the work performed by Sanofi. The FDA is due to make its decision on approval by 27 July. Given the clear negative outcome of the Advisory Committee Universe we do not expect approval of this drug in July. There was clearly interest from the FDA Committee in better characterising the safety profile of rimonabant in order to allow the drug to reach patients.	Based on the negative Advisory Committee outcome for Zimulti, we have reduced our probability of success to 30% and delayed launch until 2011 on the basis that Sanofi will use the ongoing CRESCENDO study results to re-file with the FDA. This reduces our PharmaPipelines NPV for Zimulti in the US to EUR 0.4/share (from EUR 2/share). Total NPV for Sanofi is EUR 72.3/share. We cut out Sanofi price target to EUR 73 (from EUR 75) to reflect the significant delay to Zimulti.	Sanofi presentations on rimonabant safety & efficacy Sanofi presentations on rimonabant safety & efficacious in obese and diabetic patients. Sanofi thinks all patients with history of depression, suicidal sanofi's message was that rimonabant was efficacious in obese and diabetic patients. Sanofi thinks all patients with history of depression, suicidal ideation, on anti-depressant therapy or on anti-epileptic therapy should be excluded in the US label. However, they also clearly stated their view that a racial link between suicidality and rimonabant has not been established. There have been 2 suicides on rimonabant the potential benefits and attempts on placebo (0 on rimonabant). They pointed out that the safety profile of any drug can only be interpreted in light of the potential benefits and a medical need. Overall Sanofi defended the psychiatric side-effects profile of rimonabant. They also disagreed with some elements of FDA analysis on suicide which was later acknowledged as a difficulty in methodology by the FDA.	
Title (3)	Sanofi-Aventis: FDA vote against Zimulti approval			
Report Analyst (2)	Lehman Brothers			
Date (1)	17. 6/14/07			

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	Quote	(4)
	Title	(3)
Report	Analyst	(2)
	Date	(1)

OA Presentations

and CNS toxicity in animals was seen as clinically relevant as it occurred at the 20mg human dose. The FDA review of the clinical data The FDA highlighted concerns from the preclinical (animal) data for rimonabant. In particular, the high levels of seizure were a worry acknowledged the efficacy but focussed on the following risks:

- Only 441 patients have been on rimonabant for 2 years but the greatest sticking point was the number of patients on drug for 1 year where FDA guidance was a vague 1500
- The wide array of neurological events (sensory, motor, cognitive) are worrisome
- •16 seizures in trials despite exclusion of epileptics this requires further clinical investigation
- Rimonabant associated with a doubling of psychiatric side-effects and a 3-fold increase in discontinuation due to psychiatric side-effects: what will happen in a less highly screened and potentially more depressed population?
- ●The FDA disagrees with Sanoff that prior history of depressive disorders is predictive of this side-effect on rimonabant the FDA was looking at a broader definition of this side-effect

• Increased risk of suicidality (doubling) - FDA believes the drug is causal

was working on this. Also, the EMEA has not yet put all historic data in its database for Xenical and Meridia and that these drugs have 8% and Meridia 21%. Also, suicidal ideation cases on rimonabant are 27 vs Xenical 14 (launch 1998) and Meridia 15 (launch 1999). Another FDA representative reported that rimonabant is the subject of stimulated 'reporting of adverse events' because the company • European post-marketing data shows higher psychiatric events with rimonabant at 54% of all side-effects reported vs Xenical other side-effects that do not fall into psychiatric.

Yet to be identified risks

continued reliance on surrogate end-points is not good. Also the lack of effect on LDL and blood pressure is of note. They pointed out that CRESCENDO study ongoing in 17,000 patients looking at cardiovascular end-points is due to end in January 2010 and could Despite all this, they reminded the Committee that incidences of risks were low. However, weight loss has benefits in itself but answer whether weight loss is clinically relevant.

Suicide risk a focus

This compares to 30,000 people who actually commit suicide. She reminded the Committee that statistics from drug trials often highlight suicidality testimony was relatively positive for Sanofi. She made clear 10.5m Americans think about committing suicide every year. The Advisory meeting commenced with a presentation by Dr Kelly Posner, a child psychiatrist. Sanofi had to submit Zimulti data to Dr Posner's group for analysis. Dr Posner worked with the FDA on suicidality in patients using anti-depressants. Dr Kelly Posner's suicidal ideation but this is a common thought which may well not be linked to the drug.

Panel Title Following the rejection of Sanoff's obesity drug Zinn Panel FDA panel rejects Following the rejection of Sanoff's obesity drug Zinn Panel EDA panel rejects Panel EDA panel rejects Panel EDA concerns focused on unclarified saff The megative outcome also compounds our broad unclarified neurological safety risks based on prepince and panel PDA advisory committee, in recommending Zinn Characterized to warrant approval, in the context panel PDA advisory committee, in recommending Zinn Characterized to warrant approval, in the context penel PDA advisory committee, in recommending Zinn PDA advisory committee, in the context PDA advisory concern PDA advisory con	June 15, 2007 Quote (4)	Following the rejection of Sanofi's obesity drug Zimulti (Acomplia /rimonabant) by an FDA advisory committee we are downgrading our recommendation from Buy to Neutral Panel & FDA concerns focused on unclarified safety risks The negative outcome also compounds our broader industry concerns around FDA's attitude to drug safety. FDA focused heavily on the unclarified neurological safety risks based on preclinical data and inconclusive meta-analyses of psychiatric events. This highlights, increased safety hurdles that new products must now overcome and increases our concerns over products with pending safety questions at FDA (e.g GSK's Avandia and Novartis's Galvus).	The FDA advisory committee, in recommending Zimulti for non-approval focussed on the product's safety profile, which it felt was insufficiently O characterized, to warrant approval, in the context of the limited weight loss seen and what it viewed as inconclusive data on other metabolic E benefits	iscussion, the committee cited a number of areas of concern even though actual numbers of Zimutii had not been fully established: even all the absolute excess risks for CNS events was ted against Zimulti. With limited long term data, FDA was unwilling to take the risk that these inical evidence of potential neurological risks with the drug. uportantly an excess psychiatric adverse event rate (notably an increase in depression, anxiety and luding high risk patients (e.g. those with a history of depression). FDA and several panel members need psychiatric disorders who had never done so previously.	The patient population for which it is intended were predisposed to psychiatric disorders: committee highlighted that an obese patient pool was predisposed to psychiatric adverse events which increased risk to approval. Risk monitoring programmes were unlikely to be sufficient to limit use of put drug: Although Sanoff outlined a comprehensive risk monitoring programme, the panel expressed widespread scepticism that this would be able to control event rates in the real life setting.	The key industry concern in our opinion is that the FDA seems to be increasingly focusing on pre-clinical mechanism of action data Q suggestive of safety risk and even inconclusive meta-analyses, with seemingly less emphasis on whether there are robust statistically significant safety concerns highlighted in large clinical trials. Essentially the drug was considered guilty until proven innocent in this case.	In our opinion this increases safety hurdles that new products must now overcome in the US and increases level of concern over other products where
Analyst (2) 7 Merrill Lynch	June 13, 2007 throu		The FDA advisory committee, in recommend characterized, to warrant approval, in the benefits	But safety was the key concern In terms of safety, which formed the bulk of the d adverse events seen in clinical trials were low: The long term neurological side effect profile o low, trends in neurological side effects were all til safety signals could escalate over time given precl No predictors of psychiatric adverse events: In suicidality) was seen despite the clinical trials exc expressed concern that many patients experier	The patient population for which it is intende predisposed to psychiatric adverse events whi the drug: Although Sanofi outlined a comprel control event rates in the real life setting.	The key industry concern in our opinion is suggestive of safety risk and even inconclu significant safety concerns highlighted in I	In our opinion this increases safety hurdles th
77 Merrill L	Title (3)	FDA panel rejects Zimulti - downgrade to Neu					
(1) (1) 6/14/07	Report Analyst (2)	Merrill Lynch					
	Date (1)	6/14/07					

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	Quote	(4)	Quick Comment: The FDA panel's non recommendation of rimonabant is not a major surprise given the current risk adverse environment of the FDA, and the Endocrine and Metabolism division, in particular. FDA, and the Endocrine and Metabolism division, in particular. What does surprise us is the dramatic disconnect between Sanoff's persistent optimistic assessment of the FDA regulatory process for rimonabant, and the FDA's clearly negative presentation on the risk benefit assessment of the compound. The outcome of this meeting will be raise further concerns in investors' minds over the integrity of Sanoff's guidance to investors. We are having some Exanta flashbacks here. We see these investor communication issues as having far greater importance than the modest EPS changes outlined above.	In fairness, we acknowledge that the intensified risk adverse regulatory pressure has meaningfully shifted the goal posts. We doubt the recent meta-analysis suggesting an increased suicidality risk for rimonabant would have been conducted five years ago. In addition, the Endocrine and Metabolism division has experienced major shifts since the rimonabant program was initiated (Merck's Pargluva, GSK's Avandia, and change of Division head). Finally, the paucity of bariatric physicians on the panel did not aid Sanofi.	Time to US approval unclear although the panel's insistence on long time data precludes potential approval until at least 2011. Likely revenue potential in US market dramatically limited given delayed entry, and likely intensified competition. We believe that the EMEA reaction to yesterday's meeting is likely limited. We see the potential for some label tightening in Europe but a low probability of withdrawal given the accumulated patient safety data achieved to date. Importantly, we note that the EMEA has taken a much more measured response to the ongoing Avandia furore than the FDA.	Following the negative vote of the FDA's advisory on Zimulti we put FV and recommendation under review. Assuming that Zimulti will now have severe problems to reach the US market, we will take out about 64 per share in FV. However we expect the company to introduce a deeper restructuring in order to adjust for the worse situation. Today a marked downward reaction has to be expected.	The committee rejected the drug, viewing its risk-benefit ratio as unfavorable given an increase in psychiatric problems including suicidal thoughts. Acomplia/ Zimulti is approved in Europe and sold in over 18 countries. The FDA, that usually follows its committees' recommendations, has an action date of July 26 to decide on the compound's approval.	Given the already difficult situation surrounding Plavix (generic challenge) this is particularly negative news for Sanofi. In view of the recent problems surrounding Avandia (GSK) post approval and a tainted relationship to the FDA following the problems stemming from the Ketek approval process, the market had become rather cautious on the drug recently.	Given the high unmet medical need in the indication, however, we had still been optimistic, attributing a relatively high probability for approval of 80%. That on the other hand was applied to a more cautious peak sales of about €1.5bn (about 80% in the US) compared to the company's target of USD3bn. Expecting Zimulti/ Acomplia not to receive US-approval generation of new data to support a refiling would need about two years to be generated.
t	Title	(3)	FDA Panel 14 Rimonabant 0; Pausing to Reevaluate			No Advisory committee support for Zimulti-Another Blow			
Report	Analyst	(2)	Morgan Stanley			Oppenheim			
	Date	(1)	6/14/07			6/14/07			
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Exhibit 16 Sanofi-Aventis

Analyst Report Discussion of the June 13, 2007 FDA Advisory Panel Vote

June 13, 2007 through June 15, 2007

L:C)7 _:	-CV-	10279-GBD-FM	Document 1			30/12 Pa	age 82 of 14
	Quote	(4)	The third and most important question that the FDA asked the US Endocrinologic and Metabolic Drugs Advisory Committee that it had convened was Carcording to the data available today, do you think that rimonabant has a favourable benefit/risk profile and should be approved". The answer was a resounding "no", as the experts voted 14-0 against. Hence, their position is extremely clear-cut and does not leave any room for doubt about the Garconding "no", as the experts voted 14-0 against. Hence, their position is extremely clear-cut and does not leave any room for doubt about the Garconding final decision to come from the FDA's Division of Metabolism and Endocrinology Products (DMEP). The FDA's verdict is due on 26 July at the latest — Zimulti (rimonabant) is bound to be rejected. This rejection will mean that more clinical trials will be needed to investigate the product's safety profile further, particularly as regards its neurological and psychiatric side effects. Although we will analyse the panel's recommendations in detail and will listen to Sanofi-Aventis's view on	the subject, a clinical trial with neurological/psychiatric safety as the primary endpoint is likely to be launched. If we consider that the product needs to be taken for 1 or even 2 years before the results can be evaluated, such a study would not be able to deliver results before the CRESCENDO study, expected in Q1 2010. We have to be careful — all we can do is make predictions — and think that Zimulti will suffer a major delay as non-approval will mean that another standard regulatory review will be required. We can also wonder what impact this decision from the FDA's panel of experts will have outside the US. In its press release, Sanofi-Aventis	mentioned that the product has been approved in 37 countries and is sold in 18 of these. This was a fairly positive indication on the eve of the FDA's advisory committee as some countries where the product had been used for several months (11 months in the UK) did not think it necessary to introduce tighter rules or withdraw the product from the market. Today, can these countries turn a deaf ear to this stinging 14-0 rejection by	experts including 6 endocrinologists and metabolism specialists and 4 neurologists and psychiatrists? We think this unlikely, especially as the vote is likely to make a lot of noise in the press, both general and specialistIt is reasonable to think that the product's prescriptions will be tightly regulated in most countries until morbidity data is published, probably in 2010.	The Endocrinologic and Metabolic Drugs Advisory Committee unanimously (14-0) voted against FDA approval for rimonabant in the US, saying that the 13,000 patient-rich clinical programme had not been large enough to properly characterise the safety profile of the drug. They also did not feel confident about the side-effect profile. As a consequence, panel members voted a negative recommendation to the FDA for its decision on 26 July. Usually, the FDA does not necessary follow its panels' decisions when they are positive, but follows them almost 100% when they are negative. This is a maior blow for Sanofi-Aventis and it did not seem to matter that the Advisory Committee members did not appear	familiar at all with the clinical dossier; they simply looked at what FDA representatives wanted them to focus on, i.e. only the risks. We believe that the FDA is not comfortable in approving a product that potentially could be taken by millions of Americans and did not believe that Sanoff-Aventis' management risks plan in place in Europe is feasible for the US.
t	Title	(3)	Zimulti (rimonabant) unanimously rejected by the FDA's advisory committee				Rating downgrade FDA panel voted against the approval of rimonabant in the US by 14-0	
Report	Analyst	(2)	Raymond James Euro Equities				Societe Generale	
	Date	(1)	6/14/07				6/14/07	
			21.				22.	

Exhibit 16 Sanofi-Aventis

Analyst Report Discussion of the June 13, 2007 FDA Advisory Panel Vote

June 13, 2007 through June 15, 2007

	Quote (4)	Yesterday's FDA advisory panel on Sanofi-Aventis weight loss drug Acomplia (rimonabant) decided against recommending approval of the product in the US. The panel, which voted twice 14-0, found that the safety data was insufficient and that the weight loss recorded in clinical trials did not justify the risk of psychiatric or neurological side effects. Thus, we believe that the FDA in it's final decision slated for 26 July, will be against approving the drug in the US. Given this assumption we have removed all our US sales estimates for Acomplia from our model (€1.14bn by 2011) and lowered our EPS estimates going forward accordingly. Moreover we have reduced our NPV value for Acomplia from €4.2 to €0.8 and see furthe downside potential for the shares from here.
	Title (3)	FDA advisory committee meeting votes against approval of Acomplia
Report	Analyst (2)	WestLB Equity Markets
	Date (1)	23. 6/14/07 WestLB Equity Markets

Notes and Sources:

This exhibit includes all uniquely-titled English-language, company-specific, non-technical reports issued during the period that NERA was able to obtain from counsel or purchase from Reuters Knowledge or Thomson Investext.

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Exhibit 17 Sanofi-Aventis

FDA Advisory Panel's 14-0 Vote Against Rimonabant on 6/13/07

Changed Analysts' View Regarding Rimonabant's Approval and Sanofi's Expected Revenues June 11, 2007 through June 15, 2007

	Report(s) on 6/	Report(s) on 6/11 and 6/12 Prior to 6/13 Vote of FDA Advisory Panel				Did Analyst's Approval	Did	Did Analyst
		But Following 6/11 Release of FDA Brief	First Rep	First Report Following 6/13 Vote of FDA Advisory Panel	Analyst's	View	Analyst	He Removed
	Report Date and		Report Date and		Most Likely Outcome	Become Less	Expect Non-	US Zimulti
Analyst 1	Title	Quote	Title	Quote	Prior to Vote	Favorable	Approval?	Estimates?
(1)	(2)	(3)	(4)	(5)	(9)	(7)	(8)	6
1. Citigroup	6/12/07 FDA states Zimulti (Acomplia) doubles suicidality rate in Advisory Committee briefing documents	Yesterday Food & Drug Administration (FDA) briefing documents confirmed our suspicions: The approvable letter in 2006 was due to the FDA's "concern about [an] increased frequency of psychiatric adverse events, including suicidality". Risk-Benefit Ratio Skewed To Downside— Considering modest weight loss and some weight regain, along with the concern of widespread use despite a risk management program, the risk-benefit is unclear. This could lead to a mixed at best Panel and an approvable letter while the FDA waits for risk benefit proof from the 17,000 patient mortality trial (CRESCENDO) due in 2010.	6/14/2007 Mission Unaccomplished	Food & Drug Administration (FDA) advisory panel unanimously reject Acomplia as unsafeThe FDA advisory committee voted unanimously 14-0 that there is insufficient data to prove Zimulti is safe, and voted 14-0 against allowing U.S. approval as a weight loss drug. The use as a diabetic drug was also ruled out at the start of the panel. Double suicidality risk an underestimate — As previously stated, predictable neuropsychiatric sideeffects such as suicide risk considered an underestimate as psychiatric withdrawn patients were not followed up and depressed people excluded (30% prevalence). Moreover, the original NDA had a single suicidality case, but upon FDA requested reexamination, the original data had 54 cases. No U.S. Zimulti until 2012— With the next trial ADAGIO not a regulatory endpoint, CRESCENDO the 17,000 patient, 5-year mortality trial will answer the risk-benefit concern. With 6,000 recruited in 18 months, we see difficulty reaching 17,000 & a resubmitted NDA until 2012, now that 4 cases of Zimulti associated suicide are publicly known. Suicide fears & competitors may pare any eventual U.S. sales.	At best a mixed-panel	Yes	ξε	2

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June 11, 2007 through June 15, 2007

	IN THE STATE OF THE OF THE					I over A	7:2	Cox Thot
	B	Report(s) on with and witz that to with you of the Aurison'y range. But Following 6/11 Release of FDA Brief	First Rep	First Report Following 6/13 Vote of FDA Advisory Panel	Analyst's	Approvat View	Analyst	Say 1 mat He Removed
	Report		Report		Most Likely	Become	Expect	US Zimulti
	Date and		Date and		Outcome	Less	Non-	Sales from
Analyst ¹	Title	Quote	Title	Quote	Prior to Vote	Favorable	Approval?	Estimates?
(1)	(2)	(3)	(4)	(5)	(9)	(7)	(8)	(6)
2. Deutsche Bank	6/11/07 FDA briefing books highlight Zimulti safety concerns	FDA briefing books raise concerns over Zimulti adverse events Given other therapeutic options for weight loss, and a lack of data to support clinical outcomes (mortality etc.), non-approval is clearly a possibility FDA briefing books raise concern over infrequent but serious adverse events In the absence of clinical trial data or evidence supporting a clinical outcome benefit there remains significant risk (>30%) that the FDA panel does not recommend Zimulti for approval. Best case scenario appears to be approval with significant risk warnings. Approval with boxed warnings highlighting the potential risk of neurological adverse events and suicidality will limit revenue potential Relative to expectations, there appears to be a significant risk of Zimulti non-approval, based on FDA briefing books Based on the draft questions and the data published within the briefing books, we believe there is a significant (>30%) probability of non approval. The most likely outcome, in our view, is a recommendation for approval with substantial risk warnings and a high likelihood of a boxed warning or patient register	6/14/07 Approval of Zimulti for obesity rejected by FDA panel	Removing US Zimulti forecasts reduces 2008-12E EPS by 5-6% With the potential for an Acomplia EU recall mitigated by adaptions to scale following the FDA panel's negative stance on Zimulti in the US, we project a potential net 8% downside to SASY's valuation. FDA panel reject approval of Zimulti based on safety concerns The FDA Endocrinology and Metabolic Drugs Advisory Committee voted unanimously (14:0) to reject the approval of Zimulti. Whilst the panel accepted that Zimulti provided a significant weight loss benefit, it had a number of concerns surrounding safety. Whilst the panel concurred with the FDA's analysis of the magnitude of the increased risk of sucicidality (HR 1.9), psychiatric events (HR 1.9) and serious neurological events (HR 1.7) shown by Zimulti 20mg relative to placebo, it felt that the high discontinuation rate likely under-estimated these risks.	Possibly Non- approval; at best an approval based upon patient registraion/ boxed warnings	ζes .	√es √es	Yes

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FDA Advisory Panel's 14-0 Vote Against Rimonabant on 6/13/07

Changed Analysts' View Regarding Rimonabant's Approval and Sanofi's Expected Revenues

June 11, 2007 through June 15, 2007

lyst at	ifi T	12 C	3- U	BD-FW Document 186-1 Filed 04/30/12 Fag
Did Analyst Say That He Removed	US Zimulti	Sales from C Estimates?	(6)	Unclear
Did Analyst	Expect	Non- Approval?	(8)	Yes
Did Analyst's Approval View	Become	Less Favorable	(7)	Yes
Analyst's	Most Likely	Outcome Prior to Vote	(9)	Approval with a black box warning
First Report Following 6/13 Vote of FDA Advisory Panel		Onote	(5)	Our bet on Acomplia has not worked out, FDA advisory committee voted 14 – 0 against approval at this time as it considered more safety data was required. No dispute over efficacy. If investors can hang on then the Plavix bet is still very much intact. We cut our rarget price to EUR80. We are cutting back our Acomplia sales forecast by c. 60% in 2010 to EUR800m, reflecting higher risk that this drug will never make it through the FDA and the delay. The FDA committee has not followed Europe, which is perhaps surprising to us. But without going into too much detail; efficacy is not in question but safety data is just unclear. It looks like we will have to wait for CRESCENDO study data in 2010, which looks at mortality and outcome data as well as safety. This suggests initial launch investment costs in the US will not bear fruit. And this is likely to affect near term margin. Looking to the future, FDA are likely to deny full approval at the end of July. However, we still expect Plavix litigation to go in favour of Sanofi and this should have a plus 5 to 10% effect on the stock.
First Rec	Report	Date and Title	(4)	6/14/07 Sanofi- Aventis (Buy) - Morning meeting summary
Report(s) on 6/11 and 6/12 <u>Prior</u> to 6/13 Vote of FDA Advisory Panel But Following 6/11 Release of FDA Brief		Onofe	(3)	Acomplia/Zimulti: FDA has no issues with efficacy. Sanofi are asking for a diabetes indication as well as an obesity indication. FDA has potential issues with suicide ideation and neurogical events. Key issue: Will FDA view suicide risk bearable given benefits and risk management plan that Sanofi suggests? On balance, we think committee will vote positive and advise Buy We are mainly concerned about the FDA view on the suicide risk. However we note it is mainly in ideation (39/6802 cases on 20mg vs 13/2909 on placebo) not on suicide attempts which are better only 4/6802 vs 7/2909 on placebo. Given this and the fact that the 7 obese studies taken together did not show a higher risk (only when pooled with the schizophrenia and smokers studies) we believe on balance this is manageable. On balance, we still think FDA comittee are likely to vote to approve the drug with a possible black box warning on suicide risk and a contraindication in any high risk populations for neurogical/psychiatric conditions. While the CNS side effects do seem to be significant, we think on balance they should be manageable.
Report(s) on 6		Date and Title	(2)	Acomplia Efficacy fine. Possible suicide issue. On balance, drug still likely to be approved. Buy ahead of meeting.
		Analyst 1	(I)	3. Dresdner Kleinwort

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Exhibit 17 Sanofi-Aventis

EDA Advisory Panel's 14-0 Vote Against Rimonabant on 6/13/07 Changed Analysts' View Regarding Rimonabant's Approval and Sanofi's Expected Revenues

June 11, 2007 through June 15, 2007

Pirst Report Following 6/13 Vote of FDA Advisory Panel Analyst's Did Analyst's View Analyst Date and Analyst Date and Analyst's View Analyst Date and Analyst Date and Analysis Date a					Follow	Following the 14-0 Vote:	Vote:
Prior to Vote Prior to Vot	Report(s) on 6/11 and 6/12 <u>Prior</u> to 6/13 Vote of FDA Advisory Panel But Following 6/11 Release of FDA Brief	First Repor	t Following 6/13 Vote of FDA Advisory Panel	Analyst's	Did Analyst's Approval View	Did Analyst	Did Analyst Say That He Removed
Characterizes are securated on the CRESCENDO ratio and a much more include in our model the works. Characterizes are securated on the CRESCENDO ratio and more include in our model the works. Characterizes are securated on the currents and the currents of the currents and the currents an		Report Date and		Most Likely Outcome	Become Less	Expect Non-	US Zimulti Sales from
6/14/07 FDA advisory committee requires more safety data for Approval Acomplia Acomp	Quote	Title	Quote	Prior to Vote		Approval?	Estimates?
Rating Acomplia Acomplia/S advisory committee was unanimous that Neutral - FDA, sadvisory committee was unanimous that Acomplia/S approving the drug at this stage. Prospects Sanofi-Aventis is unlikely to be in a position to answer the FDA panel's questions before 2010 The panel's concerns notably included the need for patient follow-up longer than the two years so far required by the FDA as well as better pre-specified characterisation of side effects. This means that SAN is unlikely to be in a position to address the panel issues before the outcome of the 17,000 patient CRESCENDO trial is 2010-2011 and may also have to amend existing phase IV trials and/or initiating new ones We now factor our worst-case scenario on Acomplia in SAN's model Pending the outcome of the CRESCENDO trial, we now include in our model the worst-case scenario for Acomplia which includes no sales in the US and a much more limited ramp up for the	(3)	(4)	(5)	(9)		(8)	(6)
tion its side ay, may	rofile n the ts. nave urselves	ade to - FDA ote lia's ts	Acomplia The FDA's advisory committee was unanimous that the currently available data insufficiently characterizes the safety profile of rimonabant (Acomplia/Zimulti) and hence voted against approving the drug at this stage.	with a black box warning			
	psychiatric/neurological side effects seen with Acomplia 20mg are "clinically important" (question 1b), including an increase in suicidality which appears no higher than SSRI antidepressants. However, we still believe the balance of benefits versus risks favours Acomplia (question 3a). We still anticipate a requirement for a blackbox warning on psychiatric and neurological side effects excluding patients with a history of depression (40% of the cases of suicidality) together with tight risk-management and a pharmacovigilance programme. The debate is likely to be heated on Wednesday, especially following the Avandia issue. The 14-member panel vote in the evening of 13 June may be close, which would extend the market's nervousness until 26 July.		Sanofi-Aventis is unlikely to be in a position to answer the FDA panel's questions before 2010. The panel's concerns notably included the need for patient follow-up longer than the two years so far required by the FDA as well as better pre-specified characterisation of side effects. This means that SAN is unlikely to be in a position to address the panel issues before the outcome of the 17,000 patient CRESCENDO trial in 2010-2011 and may also have to amend existing phase IV trials and/or initiating new ones We now factor our worst-case scenario on Acomplia in SAN's model Pending the outcome of the CRESCENDO trial, we now include in our model the worst-case scenario for Acomplia which includes no sales in the US and a much more limited ramp up for the product in Europe.				

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Exhibit 17 Sanofi-Aventis Sanofi-Aventis FDA Advisory Panel's 14-0 Vote Against Rimonabant on 6/13/07 Changed Analysts' View Regarding Rimonabant's Approval and Sanofi's Expected Revenues June 11, 2007 through June 15, 2007

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	Vote: Did Analyst O	Say That He Removed	US Zimulti Sales from	Estimates?	(6)	Ž
	Following the 14-0 Vote: Ivst's Did	Did Analyst	Expect Non-	Approval?	(8)	χ S
	Follo Did Analyst's	Approval View	Become Less	Favorable	(7)	₹ S
S		Analyst's	Most Likely Outcome	Prior to Vote	(9)	close call
Changed Analysts' View Regarding Rimonabant's Approval and Sanofi's Expected Revenues June 11, 2007 through June 15, 2007		First Report <u>Following</u> 6/13 Vote of FDA Advisory Panel		Quote	(5)	News: The FDA advisory committee voted 12 to 0 against recommending rimonabant (Acomplia) for approval Implications: The FDA is to issue its verdict on 26 July and it is bound to follow the committee's recommendation. Negotiations will then take place between sanofiaventis and the FDA concerning the additional clinical trials that could be supplied to the regulator, but we now see very little hope of the product eventually being approved in the US The announcement on Acomplia, underlines the sometimes -random nature of the FDA's decisions (reflecting the political context), and could also take a toll on the sector and delay its return to favour. Following yesterday's slide, sanofi-aventis's valuation has now reached a floor for the sector (9.9x 2009) prospective earnings), but it should appreciate if the Plavix trial verdict is positive (anticipated between now and October 2007). Given Acomplia's failure in the US and the lack of growth drivers for post-2012, the group could be prompted into a strategic review in the near future. This process could be accelerated by Total's withdrawal or the sudden arrival of a new shareholder along the lines of Bernard Arnault's entry into Carrefour.
ding Rimonab te 11, 2007 thr		First Rep	Report Date and	Title	(4)	6/14/07 What strategic alternatives after the failure of Acomplia? Acomplia? What strategic alternatives after the failure of Acomplia?
<u>Changed Analysts' View Regardir</u> <u>June</u>		Report(s) on 6/11 and 6/12 Prior to 6/13 Vote of FDA Advisory Panel But Following 6/11 Release of FDA Brief		Quote	(3)	- The FDA has published briefing documents from 13 June advisory committee. - They include a complete analysis of suicidal tendencies attributable to rimonabant. Implications: Questions addressed to experts focus particularly on suicidal tendencies. However, besides the absence of cases of actual suicide with the product, there were four cases of suicide attempts in patients taking rimonabant, vs. seven with the placebo However, in a difficult context after the media hype on the side effects of Avandia (GSK), the verdict could go either way in our view, although logically the product should be approved.
		Report(s) or	Report Date and	Title	(2)	6/12/07 Suspense continues on rimonabant
				Analyst 1	(1)	Si XIS

Sanofi-Aventis Exhibit 17

Changed Analysts' View Regarding Rimonabant's Approval and Sanofi's Expected Revenues FDA Advisory Panel's 14-0 Vote Against Rimonabant on 6/13/07

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	Vote:	Say That He Remove	US Zimulti L	Sales from	Estimates?	(6)	Yes	Ŝ
	Following the 14-0 Vote:	Did Analyst	Expect	Non-	Approval?	(8)	Yes	Yes
	Follo	Approval	Become	ress	Favorable	(7)	Yes	Yes
sə		Analyst's	Most Likely	Outcome	Prior to Vote	(9)	"If's a very close call"	Difficult to tell
Changed Analysts' View Regarding Rimonabant's Approval and Sanofi's Expected Revenues June 11, 2007 through June 15, 2007		First Report Following 6/13 Vote of FDA Advisory Panel			Quote	(5)	Following the negative outcome of the FDA Advisory committee meeting we have removed US Zimulti from our Sanofi-Aventis model. Although we accept the ongoing clinical study program may ultimately result in US approval at some time in the future, we believe the current FDA endocrinology team has no desire to become responsible for Zimulti on their watch.	The third question that the FDA asked the US Endocrinologic and Metabolic Drugs Advisory Committee that it had convened was "according to the data available today, do you think that rimonabant has a favourable benefit/risk profile and should be approved". The answer was a resounding "no", as the experts voted 14-0 against The FDA's verdict is due on 26 July at the latest — Zimulti (rimonabant) is bound to be rejected.
ding Rimonal ne 11, 2007 th		First Re	Report	Date and	Title	(4)	6/14/07 Negative Zimulti vote; downgrading to Neutral	6/14/07 Zimulti (rimonabant) unanimously rejected by the FDA's advisory committee
Changed Analysts' View Regarding June 1		Report(s) on 6/11 and 6/12 Prior to 6/13 Vote of FDA Advisory Panel But Following 6/11 Release of FDA Brief	ď		Quote	(3)	• FDA published briefing documents on Zimulti (formerly Acomplia) ahead of the July 13th panel (this Wednesday). • We now have a clear picture of Zimulti's difficult path to market. The risk that the drug could increase suicide rates is suspected but clinical data show no difference between Zimulti and placebo. • On the positive side, the FDA does conclude that Zimulti gives "statistically and clinically meaningful weight loss", but must judge the risk-benefit with respect to the increased suicidality risk. It's a very close call. Risks to our rating We forecast US approval for Acomplia in H2 2007. US approval cannot be guaranteed and could be subject to further delay.	Yesterday evening, the FDA published on its website the briefing document for Acomplia that will be presented to the advisory committee experts on 13 June After reading this document, as well as the accompanying letter, we think it is very difficult to tell what conclusion the advisory committee will draw.
		Report(s) on 6/	Report	Date and	Title	(2)	6/11/07 FDA Focus on Zimulti Suicidality Risk- ALERT	6/12/07 2 SANOFI- AVENTIS - Acomplia/Zim ulti: a 'neurological' dossier that is a first for an obesity treatment - 12th June,
				,	Analyst 1	(1)	6. JP Morgan	7. Raymond James Euro Equities

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FDA Advisory Panel's 14-0 Vote Against Rimonabant on 6/13/07

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June 11, 2007 through June 15, 2007

	Report(s) on	Report(s) on 6/11 and 6/12 <u>Prior</u> to 6/13 Vote of FDA Advisory Panel				Follow Did Analyst's Approval	Following the 14-0 Vote: lyst's Did val Did Say	Vote: Did Analyst Say That
	Report	But Following 6/11 Release of FDA Brief	First Rep Report	First Report <u>Following</u> 6/13 Vote of FDA Advisory Panel eport	Analyst's Most Likely	View Become	Analyst Expect	He Removed US Zimulti
-	Date and		Date and		Outcome	Less	Non-	Sales from C
Analyst '	Title	Quote	Title (4)	Quote	Prior to Vote	Favorable	Approval?	Estimates?
€		The pharmacovigilance data is also impressive, but we would point out these documents intended for the panel of experts involved in such a committee meeting have to be handled very carefully. The aim is to target side effects rather than to give a balanced analysis of the drug's benefit/risk profile In the past, we have often been led astray by the contents of a briefing document and the alarming tone of the expert in charge of summarising a compound's side effects. We will wait to see the final vote of the 14 experts tomorrow.	£	Although we will analyse the panel's recommendations in detail and will listen to Sanofi-Aventis's view on the subject, a clinical trial with neurological/psychiatric safety as the primary endpoint is likely to be launched. If we consider that the product needs to be taken for 1 or even 2 years before the results can be evaluated, such a study would not be able to deliver results before the CRESCENDO study, expected in Q1 2010. We have to be careful — all we can do is make predictions — and think that Zimulti will suffer a major delay as non-approval will mean that another standard regulatory review will be required. It is reasonable to think that the product's prescriptions will be tightly regulated in most countries until morbidity data is published, probably in 2010.				

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specific indication (perhaps more restrictive, to only type 2 diabetic patients) WITH a warning on

psychiatric side-effects.

Changed Analysts' View Regarding Rimonabant's Approval and Sanofi's Expected Revenues FDA Advisory Panel's 14-0 Vote Against Rimonabant on 6/13/07 June 11, 2007 through June 15, 2007 Sanofi-Aventis Exhibit 17

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		Vote:	Did Analyst	Say That - He Removed O	US Zimulti	Sales from	Estimates?	(6)	No																	
		Following the 14-0 Vote:		Did Analyst	Expect	Non-	Approval?	(8)	Yes																	
		Follor	Did Analyst's	Approval View	Become	Less	Favorable	(7)	Yes																	
ies				Analyst's	Most Likely	Outcome	Prior to Vote	(9)	Approval with blackbox	launch	remains uncertain															
g Rimonabant's Approval and Sanofi's Expected Revenues	through June 15, 2007			First Report Following 6/13 Vote of FDA Advisory Panel	1		Quote	(5)	The Endocrinologic and Metabolic Drugs Advisory Committee unanimously (14-0) voted against FDA approval for rimonabant in the US, saying that the 13 000 nations rich clinical monabant had not been	large or purpose of the safety characterise the safety	profile of the gridge. They also did not feel confident about the side-effect profile. As a consequence, panel	members voted a negative recommendation to the	FDA for its decision on 26 July.	Usually, the FDA does not necessary follow its	panels' decisions when they are positive, but follows them almost 100% when they are negative.	This is a major blow for Sanofi-Aventis We believe	product that potentially could be taken by millions of	Americans and did not believe that Sanofi-Aventis' management risks plan in place in Europe is feasible	ioi uie O.S.							
ding Rimonab	June 11, 2007 thr			First Rep	Report	Date and	Title	(4)	6/14/07 Rating downgrade	voted against	the approval	in the US by	14-0													
Changed Analysts' View Regardin	<u>nr</u>			Keport(s) on 6/11 and 6/12 <u>Frior</u> to 6/13 vote of FDA Advisory Fanel But Following 6/11 Release of FDA Brief	6		Quote	(3)	Acomplia should be approved in the US and a number of Phase III trial results are to be announced shortly at scientific meetings	The FDA has released early the documents for its	Advisory Commutee meeting on 13 June. They highlight the efficacy of rimonabant 20mg. but also	focus very much on the CNS risks (depressive	disorders, suicidal thoughts, anxiety), which is the reason behind the Feb. 06 approvable letter	11.	We ultimately expect the experts to recommend rimonabant for approval, albeit in very specific	populations with the highest risk, like	also expect the experts to vote in favour of a	serious warning about the CNS risks (black box on suicidal risk?).		The FDA does not question at all the efficacy of the product but how side-effects could be managed in	practice. The FDA explicitly recognizes that the safety	database for filtiolabatic is large and growing and that the company has initiated large clinical trials to	evaluate the effect in reducing cardiovascular morbidity (e.g. CRESCENDO, which has already	recruited 8,000 patients on the 17,000 planned). We	think the panel will vote in favour of a very	specific indication (perhaps more restrictive, to
				Keport(s) on 6/ I	Report	Date and	Title	(2)	6/12/07 FDA documents	earlier,	nigningni Cins side-effects									6/12/07 The FDA has	specifically	questions for	its Advisory			
							Analyst ¹	(1)	8. Societe Generale																	

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Exhibit 17

Sanofi-Aventis

FDA Advisory Panel's 14-0 Vote Against Rimonabant on 6/13/07

Changed Analysts' View Regarding Rimonabant's Approval and Sanofi's Expected Revenues

June 11, 2007 through June 15, 2007

Following the 14-0 Vote:

Approval Did Say That View Analyst He Remover Become Expect US Zimulti Less Non- Sales from Favorable Approval? Estimates? (7) (8) (9)	Yes Yes	9 9 4
Analyst's Most Likely Outcome Prior to Vote (6)	Increased risk of negative AdCom vote	Total number of "Yes":
First Report Following 6/13 Vote of FDA Advisory Panel sport te and Title Quote (5)	Yesterday's FDA advisory panel on Sanoff-Aventis weight loss drug Acomplia (rimonabant) decided against recommending approval of the product in the US. The panel, which voted twice 14-0, found that the safety data was insufficient and that the weight loss recorded in clinical trials did not justify the risk of psychiatric or neurological side effects. Thus, we believe that the FDA in it's final decision slated for 26 July, will be against approving the drug in the US. Given this assumption we have removed all our US sales estimates for Acomplia from our model (£1.14bn by 2011) and lowered our EPS estimates going forward accordingly. Moreover we have reduced our NPV value for Acomplia from €4.2 to €0.8 and see further downside potential for the shares from here.	Total num
First Rep Report Date and Title (4)	6/14/07 FDA advisory committee meeting votes against Acomplia	
Report(s) on 6/11 and 6/12 Prior to 6/13 Vote of FDA Advisory Panel But Following 6/11 Release of FDA Brief Report Date and Title (2) (3)	As outlined in the approvable letter for Acomplia/Zimulti (rimonabant) from February 2006, the FDA is concerned about the increased frequencies of psychiatric adverse events, including suicidality Although only two completed suicides during the clinical trials by participants treated with Acomplia were reported it appears that according to an analysis conducted by a team of the University of Columbia possible and/or definitive cases of suicidality did outnumber the cases for those on placebo vs. active treatment by three to one. As such we believe that there is an increase risk that the FDA advisory committee meeting which is scheduled for tomorrow, 13 June, is advising against approving Acomplia in the US.	
Report(s) on 6/1 Report Date and Title (2)	6/12/07 FDA advisory committee briefing material does not bode well for US approval	
Analyst ¹ (1)	9. WestLB Equity Markets	

Notes and Sources:

This exhibit includes uniquely-titled English-language, company-specific, non-technical reports issued during the period that NERA was able to obtain from counsel or purchase from Reuters Knowledge or Thomson Investext.

List of analysts is limited to those who published a Sanofi report on 6/13/07 through 6/15/07, as well as one with meaningful approval-related comments on 6/11/07 or 6/12/07. Excludes UBS who ceased Sanofi coverage on 6/12/07. Exhibit does not include any analyst reports published on 6/11/07 prior to the release of the FDA briefing documents.

² Reuters lists the date of this report as 6/13/07, however the date listed in the report itself is 6/12/07.

Case 1:07-cv-102	279-GBD-FM	Doo	ument 188-1	Filed 04/30/12	Page 93 of 141
Case 1:07-cv-102	Did the Analyst Identify Any - Identify Any - Major Concerts Other Than at Information T	(OI)	OH CHI CHI CHI CHI CHI CHI CHI CHI CHI CH	yes	
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iring Which I	that the FDA Requested No New Data	<u>6</u>	ou	ou .	
Exhibit 18 Sanofi-Aventis Sanofi-Aventis Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said, "In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant" February 24, 2006 through February 28, 2006 With Regard to What Was I	Quote	(+)	Acomplia Timelines: Our initial assessment to attribute the non-approvable letter in smoking to safety concerns could be incorrect; the culprit could be insufficient efficacy in this setting. Hence a 2H'06 launch looks plausible. Further discussions with the FDA in March should determine how soon the US launch can occur. An FDA Panel (and thus further delays) remains a possibility, we think how soon the US launch can occur. An FDA Panel (and thus further delays) remains a possibility, we think soomercial potential. FDA language in the action letter 'no further study for OBESITY' doesn't bote well for a claim beyond weight loss, which would restrict reimbursement. Acomplia's contribution to CV risk could turn out to be overrated; in a real-life setting without lifestyle changes such risk reductions may be hard to achieve Our Acomplia forecast (1.6bn euros for 2010) is unchanged by the forecast requires a diabetes label or outcome data.	Highlights Yesterday, we hosted a conference call with Dr. Louis Aronne Dr. Aronne also co-authored last week's RIO-North America original contribution which appeared in the Journal of the American Medical Association. Our conference call focused on the weight management market and the potential for pharmacotherapy—in particular, of Sanofi-Aventis's Acomplia. Dr. Aronne's comments were consistent with our view of Acomplia as a major advancement in cardiovascular risk factor management and suggested that if Acomplia fits the profile that Dr. Aronne has in mind, our view of Acomplia's €3.9 bn potential in 2010 could prove conservative	
		<u> </u>	Eamings Forecasts Trimmed, Acomplia Uncertainty Persists	Sanofi-Aventis: Expert Opinion Acomplia Represents a Paradigm Shift in Weight Management	
	Report Analyst	\mathfrak{T}	Bear Stearns	Bernstein Research	
	Date	Ξ	1. 2/28/06	2. 2/24/06	

Nothing

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With Regard to What Was Requested of Sanofi in the Approvable Letter, the Analyst Said:

Exhibit 18

Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said, Sanofi-Aventis

"In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant"

February 24, 2006 through February 28, 2006

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(1)	(2)	(3)	(†)	(5)	(9)	(7)	(8)	(6)	Ü
			Investment Conclusion In the coming months, a series of catalysts will continue to emerge that could drive outperformance: approval of Acomplia (weight management) once Sanoff resolves concerns in the approvable letter						
			Details What are your key concerns on Acomplia's safety and tolerability? Dr. Aronne did not consider tolerability an issue for Acomplia: with roughly13,000 patients tested in clinical trials for Acomplia, the product has shown good tolerability. The safety risks concern the unknown risks which may energe from usage in one million people, and this is the thing that would be most interesting to know. Depression was a notable side-effect in Acomplia trials. However, it is difficult to show the exact cause of depression in weight-loss trials						
			What is the whisper in the scientific community in terms of what is happening at the FDA with Acomplia? Dr Aronne said he did not know what was in the approvable letter and could not comment on it.						
			Risks Listed below we have outlined what we see as major risks to our outperform rating on Sanofi-Aventis: • Addressing the Acomplia approvable letter may take longer than the "months" that Sanofi expects						

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Date	Analyst	Title	Quote	No New Data	Clinical Data	Trial	Trial	a New Trial	_
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2/27/06	Bernstein Research	Sanoff-Aventis: Q4 2005 Results - In Line; Resolution of Acomplia or Plavix Controversies to Drive Returns in	Acomplia continues to show signs of mega-blockbuster potential; Sanofi affirms "months, not years" stance and that no further trials are necessary for approval. Acomplia does not require any more trials to comply with the requirements of the FDA's approvable letter. Sanofi plans to launch in the U.S. and the first set of European countries in H2.06. This guidance is in sync with the "months, not years" reassurance that we thought many in the market were missing or did not accept after the February 17 announcement of an approvable letter in weight management.						
		2000	Resolution of both Acomplia (launch) and Plavix (settlement or court victory) within a year's (sic) we expect will drive the stock to the 90 euro level and beyond.						
			Exhibit 2: Sanoff-Aventis Catalysts for 2006: Q2 2006 - Acomplia: Launch in the US Q3 2006 - Acomplia: Approval and launch in the EU						
			An Acomplia Discussion Dominated the Analyst Presentation- From Here, We Wait for Resolution at the FDA At the media and analyst presentations, Sanoff-Aventis presented slides on Acomplia launch, positioning and life-cycle management in an attempt to reassure investors in the face of uncertainty over the contents of the weight-management FDA approvable letter from February 17						
			Acomplia has been the focus of perhaps an unprecedented amount of scientific attention We believe this high level of scientific interest is suggestive of Acomplia being a paradigm shift in the way cardiovascular risks are managed.						

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			Sanofi confirmed that it is not required by the FDA approvable letter to perform further trials, and therefore laid out its planned launch timetable for the drug, with US and initial European launch at the end of this year.						
			The commentary during the results provides the "months, not years" reassurances that we thought many in the market were missing. Life-cycle management plans from now to 2011 were clearly laid out, and we maintain that a company would not spend this amount on a drug unless the drug were likely to be a megablockbuster Investor questions focused on the contents of approvable letter, timing of the next information release on Acomplia, and						
			why sanon is so confident Acompta will be such a big drug. Sanon retused to answer questions related to the content of the approvable, claiming as we had anticipated that it did not to want to damage relations with the FDA since it has not yet met with the FDA to discuss the approvable letter. The information provided in the analyst presentation gave us comfort on our model assumptions, and we maintain our forecast of €3.9 bn by 2010E						
			Risks: Listed below we have outlined what we see as major risks to our outperform rating on Sanofi-Aventis: • Addressing the Acomplia approvable letter may take longer than the "months" that Sanofi expects						
2/27/06 Be	Bernstein S.	Sanofi-Aventis:	 Based on considerations explored in previous calls, we feel that each franchise is sound. 						
2		Analysis Update	Acomplia: we see 80% probability that the FDA approves Acomplia; Acomplia thereafter heads to >to >e4 bn potential. Our base case (75% probability) assumes Acomplia launches by year end and becomes a roughly e4 bn product in 2011. Our downside outcome (5%) is that Acomplia never launches and generates €0 bn in 2011. Our upside outcome (20%) is that Acomplia generates €8 bn in 2011. Our base case for Acomplia may seem like an upside outcome; we note that more than one expert on conference calls with us has predicted that Acomplia could be bigger than I sticked.						
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Case 1:07-cv-102	279-GBD-FN	<u>/</u> 1	Document 1	88-1	. Filed	04/30/	12 Page 97 of 141
Case 1:07-cv-102	Did the Analysty Identify Any Concerts Major Concerts Other Than ad Possible Data C Information T	(10)	yes		ou	no	on
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Exhibit 18 Sanofi-Aventis Sanofi-Aventis Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said, "In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant" February 24, 2006 through February 28, 2006 With Regard to What Was	Quote	(†)		rurnermore, the rak of faming to achieve rDA approval of Acompila in 2000 has risen markenly after the failure of Sanoff-Aventis' first NDA submission.	Uncertainty never helps the P/E multiple of a Pharma stock - and over 2006 sanoff-aventis is likely to have its fair share. This is tied to the label that Acomplia is likely to receive from the FDA, whether the FDA declines the Lovenox Citizen's petitionand the outcome of the patent litigation surrounding Plavix in the US.	Of greater importance was the pipeline review, which was broadly positive. Management appear confident regarding the outlook for an H2 Acomplia launch.	No news on Acomplia. Lack of news could be negative Overall, the results themselves are fine. The outlook for 2006 has the Exubera disposal included (a negative) and Acomplia launch costs as a swing factor. The lack of news on Acomplia is not great, and SAN may not give any further details out today. However, SAN does now seem to be suggesting a H2 launch rather than Q2. Webcast/meeting bam CET. Whatever information the FDA want [sic] (and it seems that no new clinical data is needed), when it has received the information, FDA can take 2 to 6 months to review it before giving another answer. This would put launch much more likely for early 2007 (or at best late 2006) as we have always forecast
	rt	(3)	Plavix trial delayed until 12 June		Tougher and Uncertain 2006	Increasing '06 EPS by 4%, Pipeline remains the focus	Sanofi-Aventis Results for FY. No news on Acomplia. Guidance includes disposal gain.
	Report Analyst	(2)	Citi		Credit Suisse	Deutsche Bank	Dresnder Kleinwort Wasserstein
	Date	(I)	3. 2/28/06		4. 2/24/06	5. 2/27/06	6. 2/24/06

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Exhibit 18 Sanofi-Aventis

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2/27/0	2/27/06 Dresnder Kleinwort Wasserstein	Sanofi-Aventis Update after n meeting Sanofi management.	with no clarity over Plavix litigation and Acomplia not likely to be launched until end 2006 or early 2007, there still remains two way risk (see our trading idea, for a few dollars more).						
7. 2/27/06	6 Exane BNP Paribas	P Acomplia again stole the show from the pipeline review	As no new clinical trial has been requested by the FDA for Acomplia in obesity, a relatively short delay can be expected. We have changed the launch date to Q3 05 [sic] in our model. We remain optimistic that the drug will be a commercial success and maintain our 2010 estimate of EUR2.1bn in sales.	ou	OII	yes	no	OU	ou
			Acomplia (obesity): Sanoff-Aventis said as much as it could at this stage regarding the FDA by saying that no new clinical trial has been requested by the FDA in obesity. This is different from the smoking cessation indication where a new trial was requested (one of the two phase III STRATUS trials had not reached statistical significance). We doubt Sanoff- Aventis will further pursue this much smaller indication, which would also add a lot of complexity to the product's positioning.						
			The company will meet with the FDA "in March" after which it will be able to be more precise on the issues at stake in obesity (which are likely to be centred on depression/anxiety cases). This lends weight to our scenario of a relatively short delay in this indication (the "Ambien CR-like" scenario). We have adjusted the launch date to Q3 05 [sic] in our model (from Q2 05 [sic], but EPS neutral). Acomplia could still be approved by mid-year, but too late for a full launch before the summer holiday. We remain optimistic that the drug will be a commercial success, and maintain our 2010 estimate of EUR2. Ibn in sales.						

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	Quote	(4)	Key issues affecting the future outlook include: expected timing and costs associated with Acomplia US launch (we estimate 4Q2006) Key Issues Acomplia: The company made little comment except for stating that it will meet with FDA in March and that no additional clinical studies were required for the obesity indication and one additional study for the smoking cessation indication. We believe that there is still a high likelihood of an FDA Advisory Committee meeting but anticipate approval for use in obesity management, alone, in time for a 4Q2006 US launch, and global sales in 2010E of EL.5 bn.		Promising pipeline Against the backdrop of an industry facing a dearth of alternative sources of growth, sanoff-aventis boasts one of the most promising pipelines. The group has three new high-growth potential molecules in the final stage of clinical trials: Acomplia (obesity treatment) Growing presence in the US The obesity drug Acomplia, which is due to be launched in the US in 2006, will be the first real test of this 'go-it alone' capability.
ort	Title	(3)	Plavix, vaccines and Acomplia the key long-term drivers; minor EPS changes post FY results	Sanofi-Aventis S.A. Competition from generic drugs intensifies	sanofi-aventis Encouraging outlook despite cost ramp-up
Report	Analyst	(3)	Goldman Sachs	IIR Group	ING
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Exhibit 18 Sanofi-Aventis Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said "In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant" February 24, 2006 through February 28, 2006 With Regard to What Wain the Amprovable Letter		- Quote	(4)	We believe the muted share price response to the Acomplia "Approvable letter" is unjustified. We're encouraged the FDA hasn't signalled major safety concerns and we believe an "Approvable" is actually a strong endorsement by the agency.	We've analysed all NCE [new chemical entity] approvable letters issued by the agency between 1997 and 2004 and the data show that 70% of Approvables convert to full approval within 12 months - strongly supportive of company guidance. Although the "Approvable" falls short of our best-case expectation, we are far from discouraged. We have moved Acomplia launch to the conservative end of guidance (Q1 2007) but our multi-billion peak sales expectation is intact Acomplia remains the key catalyst for performance. In our numbers Acomplia is worth 10 euros of value compared to 3 euros of value for the remaining patent life for Plavix in the US. We reiterate our multiples-based 81 euro price target and Doverwainth enemaining patent life for Plavix in the US.	The Acomplia approvable letter for weight loss has been received with scepticism. We're more upbeat. Two weeks ago there was no official view on Acomplia from the FDA- we had no idea how they viewed the drug. Now we know that the FDA thinks the drug is "Approvable" for weight loss. We think this is an important step forward and makes us more confident that Acomplia will reach the market, not less	Sanoff-Aventis has said little about the contents of the approvable letter other than saying they expect to convert to full approval in a matter of "months not years". The brevity of these comments has been received with some scepticism.	We decided to test the credibility of Sanoff's claims by looking at previous approvable letters issued by the FDA to judge the real outlook for drugs in this situation. We've built a database of the 64 "Approvable letters" for NCEs issued by the FDA in 1997-2004the key findings are encouraging. Our database shows that an Approval (sic) letter from the FDA is a strong and onsement for a duty. Two important facts energe. Firstly, 84% of NCE approvable letters ultimately convert in the contract of the con
	Ĭ	Title	(3)	"Approvable letter" statistics on Acomplia's side				
	Report	Analyst	(2)	2/27/06 JP Morgan				
		Date	(I)	11. 2/27/06				

to full approval...Secondly, 70% of NCE Approvable letters convert to full approval within 12 months - the timeframe

suggested by Sanofi ("months not years").

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that the FDA Requested	No New Data (5)		ou
	Quote (4)	We are satisfied that the FDA hasn't raised major safety concerns and indeed it has given an approvable letter without referring to an advisory committee. We're also comforted that Sanoff's guidance on the timeline for resolution is supported by statistics from previous approvable letters. Our worst case fear was that the depression signal in the clinical data would prompt the FDA to request further trials to examine the drug in depressed patients. Sanoff's initial response to the approval (sic) letter indicates that this worst case is now behind us. From a modelling perspective we've assumed an Acomplia launch on the conservative end of Sanoff's new guidance (January 2007) and this pushes our sales profile out by 9 months Risks to our target Our valuation assumes Acomplia reaches the market. Recent developments (the FDA approvable letter) actually increased our confidence of full approval but there is a risk that the company might not be able to satisfy the outstanding issues therefore the drug could fail to be approved. Acomplia is worth 10 euros of our valuation.	Following solid FY05 results, Acomplia's status with the FDA remains key to investor sentiment and P&L projections beyond 2006. While management would not give much away ahead of a March FDA meeting, they clearly remain highly confident of both a 2006 US launch and an attractive label. Investing in Sanofi can therefore be construed as a matter of trust We have made minimal changes to our forecasts which remain sensitive to the timing and sales of Acomplia
	Title (3)		Sanofi-Aventis (EUR 72.10) 2 - Equal weight
Report	Analyst (2)		2/27/06 Lehman Brothers
	Date (1)		12. 2/27/06

Case 1:07-cv-102	Did the Analyse Identify Any— Major Concerna Other Than a Possible Data— Information T	Docume	nt 188-1	Filed 04/3	0/12	Page 102	of 141
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Exhibit 18 Sanofi-Aventis Sanofi-Aventis Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said. "In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant" February 24, 2006 through February 28, 2006 With Regard to What Was in the Anarovable Letter	Quote	ACOMPLIA -Meeting with the FDA to discuss approvable letter for obesity indication expected over coming few weeksManagement assured that no additional obesity studies are required for approval. However, an additional smoking cessation study is neededUS launch is anticinated before the end of 2006, Also in 2006 Germany. UK, In 2007 France, Italy and Spain.	-Data from SERENADE (small diabetes study in which patients are treated for six months) may be available mid- 06. -Market opportunity – one third of US population. Significant further life cycle management studies starting.	Although FY05 results and guidance for FY06 were in line with our forecasts, the outstanding uncertainty relating to rimonabant (Acomplia obesity) and the generic threats to Plavix (stroke prevention) and Lovenox (thrombosis) remain unresolved. We therefore expect the stock to remain under pressure in the short to-medium term and maintain our Neutral rating Rimonabant - no studies required but FDA issues unknown. Little new information was forthcoming relating to the recent approvable letter for rimonabant in weight management. Management did comment that no new tradition of the recent approvable tester for rimonabant in weight management.	studies are needed for this approvarious for the state of the definition of the state of analysis would be needed. We continue to believe that a number of issues that could substantially after the commercial profile of the drug could remain outstanding. These include the CNS safety profile of the drug and cardiometabolic claims that we believe Sanoff is seeking on the label	No new studies needed for Acomplia but what about data? There was little new information of the recent approvable letter for rimonabant in weight management and non-approval for smoking cessation except management did confirm that no new studies were needed for weight management. However, it would not be drawn further on the contents of the letter nor confirm whether any new data is needed from existing studies nor whether outstanding issues related to safety or efficacy of the product as well as just labeling.	Pare 10 of 20
	Report te Analyst Title	(3)		2/27/06 Merrill Lynch Overhangs remain			
	Date	€		13. 2/2			

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Sanofi-Aventis Exhibit 18

Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said,

"In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant" February 24, 2006 through February 28, 2006 With Regard to What Was Requested of Sanofi in the Approvable Letter, the Analyst Said:
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As we have previously highlighted we believe that a number of issues could still remain outstanding at FDA: 1) The cardio-metabolic daims that Sanofi is seeking on the label are likely to remain the subject of protracted labeling discussions. 2) FDA could still require additional analysis or data for charification of either safety or efficacy issues; 3) Whether any kind of risk-monitoring programme or restrictions on the label are required, given the potential for CNS (anxiety and depression) side effects, could still be a matter for discussion. However, as we expected, management announced a delay to its US haunch plans for Acomplia to 2H 06, vs 2Q 06 previously. Our forecasts remain unchanged, assuming launch in at the beginning of 2007 and 2010E sales of Eur I.5bn Sanofi-Aventis Rimonabant 2006 commercialization is likely, Sanofi management believes. Our January 26 report documented our belief that delays <18 months have a limited valuation impact. The FDA approvable letter for obesity does not require additional clinical trial data, we understand. Our risk-adjusted '12 estimate is 1.4bn euros	ш спе жры с				that the FDA	Requested	No New		(9)		yes
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Report								Quote	(4)	As we have previously highlighted we believe that a number of issues could still remain outstanding at FDA: 1) The cardio-metabolic claims that Sanofi is seeking on the label are likely to remain the subject of protracted labeling discussions: 2) FDA could still require additional analysis or data for clarification of either safety or efficacy issues; 3) Whether any kind of risk-monitoring programme or restrictions on the label are required, given the potential for CNS (anxiety and depression) side effects, could still be a matter for discussion. However, as we expected, management announced a delay to its US launch plans for Acomplia to 2H 06, vs 2Q 06 previously. Our forecasts remain unchanged, assuming launch in at the beginning of 2007 and 2010E sales of Eurl.5bn	Rimonabant 2006 commercialization is likely, Sanofi management believes. Our January 26 report documented our belief that delays <18 months have a limited valuation impact. The FDA approvable letter for obesity does not require additional clinical trial data, we understand. Our risk-adjusted '12 estimate is 1.4bn euros
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Sanofi-Aventis

Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said, "In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant"

February 24, 2006 through February 28, 2006

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> > failure of the STRATUS EU trial to reach its primary endpoint. However, the commercial potential resides in obesity and smoking cessation is straightforward. The FDA has requested an additional clinical trial for smoking cessation, given the Like staring at cloud formations, the contents of the approvable letter for the obesity indications becomes a little less opaque as time passes. The challenge is determining what is real versus illusory. The non-approvable letter for related disorders. Here the situation is less obvious. Thus far, in the obesity setting, Sanofi has indicated that the Rimonabant- the drug formerly known as Acomplia

"Launched in months not years"

"No additional clinical data in the approvable letter is requested to gain approval for weight management"

"Situation more analogous with Ambien CR than Alvesco" "Acomplia" is unacceptable as a brand name

Continue to plan for launch in major markets in 2006

Sanofi will meet with the FDA in March after which we may receive further guidance..

Clearly, a delay relating to a glycaemia/dyslipidaemia is a far lesser concern that (sic) a delay related to rimonabant related psychiatric risk... Hence, we have maintained throughout that Sanofi would struggle to receive an indication for diabetes

Are CNS adverse events a rate limiting step to approval? Chicken or egg? or dyslipidaemia without addition (sic) clinical trial data.

investigators refer to the need for Sanoff to conduct 6-month safety trials in patients with a history of depression, concerns of the capital markets with which they spend considerable amounts of time. Conversely, given the likely high from clear whether through the phenomena of "transference", opinion leaders are merely communicating the collective or medicated with anti-depressants. We look up [sic] this conundrum as a case of the chicken and the egg. It is far The market is of course awash with speculation. Sanoff-Aventis's competitors as well as many of its rimonabant patient demand for this agent as well as the small CNS signals, these concerns may be well founded.

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Exhibit 18 Sanofi-Aventis Sanofi-Aventis Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said "In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant" February 24, 2006 through February 28, 2006 With Regard to What Wain In the Approvable Lette	Quote	Our view based on all available information is that the scope of the indications rather than CNS concerns is the primary cause for the approvable letter. We also take some comfort from historical experience. Sanofi-Aventis's regulatory record of accomplishment is upper quartile for the industry. Sanofi- Aventis's head of Regulatory affairs has prior agency experience as chair of the Metabolic and Endocrine division. In the absence of new data points, we follow the company's guidance and expect first launches before year-end. Given the long competitor lead-time, we believe that a delay of 18 months or less in time to market for rimonabant has a minimal impact on value contribution. The only risk remains that historic or future data demonstrates a strong negative safety signal that could preclude approval (of Exanta).	The Facts Regarding Acomplia in obesity, Sanoff-Aventis officially announced that no additional clinical trials have been required by the FDA. This trims the debay to a few months, and we expect haunch of the drug in Q4. Ongoing talks must either be about safety or the contents of the final label. We believe it is essential for Sanoff-Aventis to aim at winning medical positioning of this product (obesity + risk factors) and to larget its population very strictly (diabetologists strike us as the most relevant, given the quality of Rio Diabetes). Valuation and Risk • We maintain our positive stance on the stock, whose main catalysts should be more complete information about Acomplia and an increase in management's 2006 forecasts by mid-year.	• Sanoff-Aventis reported Q4 and full-year '05 EPS of EUR 1.08 (+20%) and EUR 4.74 (+26%) vs. our (and consensus) • Sanoff-Aventis reported Q4 and full-year '05 EPS of EUR 1.08 (+20%) and EUR 4.74 (+26%) vs. our (and consensus) EUR 1.06 and EUR 4.72 estimates, respectively. While the quarter was in pretty good shape overall, investor attention today is likely going to be focused on the Acomplia NDA and potential approval timeline - company saying 2H'06 laumch in the U.S Risks to the SNY story include: (1) the potential that Acomplia is not as commercially successful as we have modeled
		9	Sanofr-Aventis Confidence in 2006 Outlook	SNY: EPS Quick-takeFinancials Okay - Saying 2H'06 U.S. Acomplia Launch
	Report Analyst	E)	2/27/06 NATEXIS	Prudential Equity Group, LLC.
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Exhibit 18 Sanofi-Aventis Sanofi-Aventis Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said "In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant" Eebruary 24, 2006 through February 28, 2006		— Quote	(4)	 HIGHLIGHTS SNY's post 'approvable letter' guidance for rimonabant (aka Acomplia) is for ZH-06 launch in the US and other select territories, consistent with our modeling. We believe FDA wants to see more safety data before issuing full approval, probably culled from one or more ongoing rimonabant trials. 		all infentioned arready has a good total or what needs to happen to get the drug approved, but it is unclear when the company will she this information publicly. Our best understanding of the current situation is that the FDA wants additional safety data on rimonabant before issuing a full approval. This safety data can probably be culled from one or more of the ongoing studies, and fits within management's guidance that for weight management no "new" studies are being asked for by the agency. Whether a Class 1 or Class 2 resubmission, we feel the company has a good chance of meeting the new launch timing guidance for the weight management indication. Rimonabant's smoking cessation indication will, according to the company, require running new clinical studies, a requirement that will likely result in a considerable delay in approval. We do not yet know what the reason for the non-approvable letter was for this indication.	As we have written about previously, rimonabant is likely to launch with some form of "risk management" program that the company and FDA find mutually acceptable that will essentially meter the uptake of the drug and will track more closely adverse events as they arise.
	į.	Title	(3)	SNY: Rimonabant (aka Acomplia) Coming 2H'06 - Heavier Spending Assumptions	Lowers Our '06 and '07 EPS		
	Report	Analyst	(2)	Prudential Equity Group, LLC.			
		Date	(1)	2/26/06			

Exhibit 18 Sanofi-Aventis

Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said, "In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant"

February 24, 2006 through February 28, 2006

With Regard to What Was Requested of Sanofi in the Approvable Letter, the Analyst Said:

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	Quote	(4)	SELECT UPCOMING EVENTS • Rimonabant Regulatory Action & Launch: 2H-2006 in the US and certain EU markets, assuming all goes well [sic] regulatory agencies like FDA. Exactly how or when SNY will communicate the extent of FDA's requests, or more precise launch timing, is unclear.	The approvable letter received for Acomplia represented a first sedback on which it was difficult to guide investors. The press release and information meeting last Friday were other events that have to be judged carefully	Acomplia: an approvable letter is always a grey area for financial markets — given that its contents cannot be made public, it is unclear how long it will take for approval to be given. Although Sanoff-Aventis is now, legitimately, very careful when communicating on this subject, it is nevertheless trying to reassure. There have been two main indicators: the FDA has not requested another study and the product is set to be launched in H2 2006. However, this letter is still another question area, and thus instead of removing doubts (Plavix lawsuit, citizens petition on Lovenox, slipping tail-end of the portfolio etc.), it has added another one. Now, whatever your conviction on this subject, it is likely to continue to be an area of uncertainty, especially as long as the group has not met with the FDA to discuss the content of the letter and the work that remains to be done. However, note that we have gleaned a few pieces of information from various people, particularly concerning the question of ethnic representation in the US group in the RIO programme.
Ē	Title	(3)		SANOFI- AVENTIS: a contrasting landscape	
Report	Analyst	(2)		Raymond James Euro Equities	
	Date	(1)		17. 2/27/06 Raymond James Eur Equities	

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Sanofi-Aventis Exhibit 18

Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said,

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February 24, 2006 through February 28, 2006

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Quote (4)	In saying that it does not have to carry out another study, the group is in some way answering the problem that would arise if the FDA had raised this question — indeed, the only solution would be to carry out another trial, albeit small, including black and Hispanic populations. Although one of the group's managers conceded that there we some differences in the results for Caucasians and non-Caucasians, they are insignificant and, above all, do not require more patients. As a benchmark, it is worth noting that when Novo-Nordisk received an approvable letter for Levenir, linked mainly to the fact that the black population was under-represented in the trial, it received a class 2 type letter, which is not the case for Sanofi-Avenis. However, the group also granted that on occasions it has been surprised by the difference between the content of the approvable letter and the discussions that follow with regulatory authorities. Under these circumstances, we can but remain cautious, at least until the group meets the FDA.	In conclusion, we would prefer to wait for the meeting between Sanoff-Aventis and the FDA on the subject of Acomplia to be sure that the optimistic first impressions are confirmed, and the publication of CHARISMA results. Positive outcomes on both of these fronts would no doubt lead us to be more upbeat on Sanoff-Aventis. This will be a question of weeks.	Potential impact on forecasts 2006 guidance is for +10% in EPS at a £/8 rate of 1.25. On current FX, this means a 13% increase as it includes the capital gain on Exubera. Excluding this element, this means guidance of +11%, i.e. not so far from our estimates as 2006 will be a year of investments for the launch of Plavix (Japan) and Acomplia in H2 06.	Our base-case scenario points to a DCF value of 694.9 with conservative Acomplia estimates, for which Sanofi-Aventis got an approvable letter from the FDA, but expects to launch in H2 06.
rt Title (3)			Sanoff-Aventis Full-year results Relief on rimonabant and R&D, mixed on guidance	Sanofi-Aventis EPS upgrade More in the guidance than first appears
Report Analyst (2)			Societe Generale	2/27/06 Societe Generale
Date			18. 2/24/06	2/27/06

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Exhibit 18 Sanofi-Aventis Sanofi-Aventis Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said "In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant" February 24, 2006 through February 28, 2006 With Regard to What Was in the Americant to the Agency Call During With Regard to What Was		Quote (4)	Our base-case scenario points to a DCF of €95.2 with conservative estimates on Acomplia, for which Sanofi-Aventis received an approvable letter from the FDA but expects to launch in H2 06. Sanofi-Aventis remains our preferred stock in the sector. Buy We expect that by early May 2006, the company will have provided more details about the approvable letter on rimonabant in weight management in the US. Rimonabant/Acomplia: potential intact We will not add much to what we already wrote in our report dated 16/02/06, as we remain convinced the product will be approved by the FDA without an Advisory Committee. On Friday 17/02, Sanofi-Aventis received: A non-approvable letter for weight management The company specified that the FDA was not asking for additional clinical trial(s) in obesity but does not wish to provide more details ahead of a meeting with the Agency in March. Sanofi-Aventis now anticipates a launch in the US and other European and Latin American countries in H2 06 (vs Q2 06 initially anticipated), in line with our initial estimates. It is unlikely that the product will be marketed under the brand name Acomplia, as this is not seen as being acceptable to the FDA. However, we have no more details regarding the timing (our estimates were for a Q3 06 launch).	
	ort Teat.	(3)	Sanofi-Aventis: Building long-term value from the R&D pipeline	Vaccinated against most risks
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that the FDA Requested No New Clinical Trial (7)		yes	
that the FDA Requested No New Clinical Data (6)		ОП	
that the FDA Requested No New Data (5)		Ou	_
Quote (4)	Investment case 3-6m We think it is time for P/E multiple expansion at Sanofi-Aventis. At a 10% discount to the 2006 sector P/E ex Roche, the current share price does not value the 2006-10 new product cycle (Ambien CR, Acomplia, Multaq, SR58611, etc.). A 12-13% premium would look fair, implying a FV of €95. As time goes by, the sensitivity of SAN-AVE's share value to Plavix in the US is set to decline (NPV-€4/share). Our base case scenario points to a DCF value of €95.2 with conservative Acomplia estimates, for which Sanofi-Aventis got an approvable letter from the FDA, but expects to launch in H2 06. Sanofi-Aventis remains our preferred stock in the sector. Buy.	- SASY hopes for Acomplia launch in H2'06 - risk of slippage Commenting on Reuters, management said the FDA did not ask for additional clinical trial data for Acomplia, and still hope for an '06 US launch, more likely in H2 than Q2. We perceive a high risk of further regulatory slippage on the phia launch timing and forecast a 2007 launch. Not Statement of Risk Company-specific risks include The major drug in development for obesity, Acomplia, received an approvable letter and the reasons remain unclear.	Page 18 of 20
port	Building lon value from I pipeline	First Read: \$\) t Aventis Q4/FY'05 E in-Line; Aco Delay Sears Monn Years	
	that the FDA May Have Identify Analymethat the FDA Requested No New Trial Anower Identify Analymethat the FDA Requested No New Clinical Anow Data or Information (5) (6) (7) (8) (9) (10)	port Title (3) Building long-term And the FDA Requested An Owew Pair Clinical Data of Data Of the State of Section 1 Sector PJE state value to prair in pipeline Sector PJE state value to prair in the Sector. Buy, but expects to launch in H2 06. Sanofi-Aventis remains our preferred stock in the sector. Buy.	Port Title Date Charles Charl

Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said, Sanofi-Aventis

"In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant"

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		,	Kep Analyst	(2)	16 UBS Investment Research			
			Keport Title	(3)	Much Still to be Acomplished			
			Onote	(4)	No clear answer on Acomplia, as expected At the investor meeting, Sanof-Aventis did not satisfy questions relating to the Acomplia approvable letter, in our view. We believe the company itself will remain uncertain of the FDA's thoughts until they meet in March. That the FDA did not request further trials might be positive, but not necessarily so. Confinued caution would seem warranted until clarity is gained	Acomplia and Plavix uncertainty leave us on the sidelines With continued uncertainty over the timing of an Acomplia launch and with the Plavix US patent trial coming up (3 April start - judge-only trial), uncertainty remains high. Thus, although the stock is trading at a significant discount we continue to rate SASY Neutral 2.	Financial guidance for 2006 appears a bit more optimistic than we forecast, but we believe the business may struggle to get there if Acomplia is not launched in the US and EU until 2007, as we forecast. In our view, management did not satisfy the market's questions relating to the Acomplia approvable letter and we believe management is not certain of the FDA's thoughts. The fact that the FDA has not requested additional clinical trials in obesity sounds positive but this is not clear, given the FDA is aware of the large outcome studies underway or planned. We believe continued caution regarding Acomplia is warranted until the company has met with the FDA and is able to update the market, which might not be until the Q1'66 results on S. May. By that time the Plavix patent trial will be underway (3 April commencement) with a ruling likely in Q4, given it is a judge-only trial. These uncertainties leave us happy to remain on the sidelines for now, at least until we get clarity on the status of Acomplia. In the absence of this, we continue to rate the stock Neutral 2	We note that, historically, Sanoff-Avends management has been conservative with its guidance in the early part of the year. However we also note that guidance assumes Acomplia will launch in the US and in some major European markets in H2'06 – we expect the product will be further delayed
		that the FDA	Kequested No New Data	(2)				
	that the FDA	Requested	No New Clinical Data	(9)				
	that the FDA Requested	No New	Clinical Trial	(2)				
May Have	Requested Data Other	Than From	a New Clinical Trial	(8)				
•	Nothing N About an FDA	Request For	New Data or a New Trial	(6)				

Sanofi-Aventis

Analyst Commentary Following the February 24, 2006 9:00 a.m. Earnings Conference Call During Which Defendant Le Fur Said, "In the Approvable Letter, No Additional Trial in Obesity Has Been Requested by the Agency Regarding Rimonabant"

February 24, 2006 through February 28, 2006

		Did the	Identif	Nothing Major C	About an FDA Other T	Request For Possible	ta or Inform)[)	
	uid:)A	و				ical New Data or		(6)	
-	in the Approvable Letter, the Analyst Said:	that the FDA	May Have	Requested	Data Other	Than From	a New Clinical	Trial	(8)	
	rovable Letter,			that the FDA	that the FDA Requested	No New	Clinical		(7)	
D	in the App				that the FDA	that the FDA Requested	No New	No New Data Clinical Data	(9)	
						that the FDA	Requested	No New Data	(5)	
								Quote	(4)	As expected, the main focus of the market was on Acomplia and, also as expected, management provided little in the way of further clarity beyond that given earlier in the week, given the meeting with FDA staff to discuss their concerns in detail is not scheduled until March. Management stressed the FDA had not requested an additional study and are hopeful of a H2 launch in the US and in major EU markets. We see the risk of regulatory slippage as high and continue to forecast a 2007 launch.
								Title	(3)	
							Report	Analyst	(2)	
								Date	(1)	

Notes and Sources:

This exhibit includes all uniquely-titled English-language, company-specific, non-technical reports issued during the period that NERA was able to obtain from counsel or purchase from Reuters Knowledge or Thomson Investext.

Exhibit does not include any analyst reports published on 2/24/06 prior to the conference call.

"Q4 2005 Sanoff-Aventis Earnings Conference Call in French with simultaneous..." Business Wire, 2/24/06 6:21 p.m. (conference call time assumed to be ET); "Q4 2005 Sanoff-Aventis earnings Conference Call- Final," Voxam FD Wire,

² Qualifies for a "yes" if an analyst (1) expects an Advisory Committee meeting may be requested, (2) acknowledges the chance of a non-approval, and/or (3) identifies other non-data/information concerns re Acomplia approval (e.g. label restrictions).

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Sanofi-Aventis

Analyst Commentary Following the October 31, 2006 2:00 a.m. Earnings Conference Call

During Which Defendant Spek, in Response to a Question About Whether the Company Had Submitted Data, Said, "... As the Approvable Letter Did not Ask for New Additional Clinical Trials, Consequently it is Easier for Me to Say that We Have Not Submitted New Data in this Respect", and that Sanofi "Submitted October 26 a Complete Response to This Approvable Letter..."

Contents of Sanofi's 10/26/06	Submission	(10)	по		
Did Not Say that These May Have Been from	a New Clinical Trial	(6)	yes		
No Data from a New Clinical	Trial	(8)	по		
Submitted No New Clinical	Data	(2)	по		
Sanofi Submitted No New	Data	(9)	Ou		
a Complete Response to the Approvable	Letter	(5)	yes		
	Quote	(4)	Acomplia US Launch Delayed: Sanofi finally submitted the FDA complete response on October 26 2006 following the approvable letter received on February 17th. Assuming a 6-month PDUFA, this would imply an approval in late April 2007. In our opinion, this is a significant delay and should contribute to further downward pressure on the stock.	Uncertainty on Acomplia Persists: SASY specified that Acomplia was re-submitted on October 26, 2006. The time required for re-submission (>8 months) seems to indicate that the file included substantial additional data from the RIO studies, which should make a quick turn-around unlikely. A class-2 re-submission could still require an advisory meeting. In the absence of hard data on weight-independent benefits on cardiovascular risk factors, we remain skeptical about Acomplia's commercial potential.	SASY specified that Acomplia was re-submitted on October 26, 2006 and hence, Acomplia was a key focus of the 3Q06 Analyst call. In our opinion, four big issues that remain unresolved: 1) Why did it take so long for Sanofi to submit a complete response for Acomplia? 1. It is still unclear why it took >8 months to fulfill the FDA requests outlined in the letter, especially since the company has repeatedly stated that data from new studies was not required. The time required for resubmission seems to indicate that the file included substantial additional data from the RIO studies, which could imply a concern regarding a safety signal or the analysis of the efficacy benefit observed, in our opinion.
	Title	(3)	3Q06 FirstTake - Disappointing Sales and Acomplia Newsflow	Downgrade from Peer Perform to Underperform	
Report	Analyst	(2)	10/31/06 Bear Steams	11/1/06 Bear Steams	
	Date	(1)	10/31/06	11/1/06	

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about the	Contents of	Sanofi's	10/26/06	Submission	(10)		
	at		Have Been from	a New Clinical Trial Sı	(6)		
Submitted	No Data	from a	New Clinical	Trial	(8)		
Sanofi	Submitted	No New	Clinical	Data	6		
that	Sanofi	Submitted	No New	Data	9		
Submitted	a Complete	Response to	the Approvable	Letter	(3)		
			Ī	Quote	(f)	2) Will the NDA resubmission be a Class 1 or 2 review? It is unclear whether the FDA will provide a response within 2 or 6 months. [A Class 2 review with April 26, 2007 response] would extend well beyond the 'by year end' guidance that Sanofi had previously guided towards. A Class-2 resubmission would also leave the door open for the FDA to request an Advisory Meeting. In our opinion, a Class 2 review is more likely given the length of time taken to actually compile the necessary data for the complete response	 Has the standpoint of the FDA changed on Acomplia? We would point out that the FDA Metabolic and Endocrine Drug Products Division has a new director who was appointed recently, i.e. after SASY received its Approvable Letter. In our opinion, the new director may have a more cautious stance (especially with regard to safety)we cannot rule out the possibility of a request for an FDA advisory meeting on Acomplia during the next six months, which in turn could raise further issues to consider. Will SERENADE data result in a tangible benefit for Acomplia? Sanofi will present the [data] at the IDFWorld Diabetes Congress meeting in Cape Town (3rd-7th December 2006). The language of the company on SERENADE appeared fairly positive in terms of the outcome of the studyWe are cautious whether SERENADE would result in an additional claim for Acomplia in the treatment of diabetes.
				Title	(3)		
			Report	Analyst	(2)		
				Date	(1)		

Sanofi-Aventis

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October 31, 2006 through November 4, 2006

With Regard to What Sanofi Submitted to the FDA, the Analyst Said: that Sanofi

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	Nothing	about the	Contents of	Sanofi's	10/26/06	Submission	(10)	yes	Ou
May Have	Submitted New	Data, Analysis, but	Did Not Say that	These May	Have Been from	a New Clinical Trial	(6)	00	01
that	Sanofi	Submitted	No Data	from a	New Clinical	Trial	(8)	ОП	yes
	that	Sanofi	Submitted	No New	Clinical	Data	(7)	ОП	ou
		that	Sanofi	Submitted	No New	Data	(9)	01	Q1
	that Sanofi	Submitted	a Complete	Response to	the Approvable	Letter	(5)	yes	yes
						Quote	(4)	FY EPS guidance has been marginally increased though this could be attributable due to deferred Acomplia US launch costs as expected approval has now been pushed back to 2Q 2007 Acomplia. In Europe sales were only 11m vs our estimate of 25m. In the US management has given an update on the regulatory review process - on the 26 October 2006 Sanofi filed a complete response to the approvable letter received from the FDA. Allowing for a 6 month review period, the earliest we can now expect US approval is 26 April 2007. Up to now, management had maintained guidance to a launch in late 2006. Results of the SERENADE trial will be presented at the WDF conference in December 2006 Risk of further delays to the US approval of Acomplia. We continue to believe that the FDA is taking a more cautious stance over Acomplia's risk/benefit profile versus the European regulators.	Acomplia to the rescue? Management confirmed that they had submitted a final response to the FDA approvable letter on October 26, 2006. Assuming no major additional clinical trial data were required, a Class I resubmission could result in approval on or around December 26. We continue to remain relatively cautious regarding the outlook for Acomplia, forecasting revenue of EUR 1.2bn in 2010, relative to consensus forecasts of EUR 1.5bn
					rt	Title	(3)	Results: Snap reaction	Q3 EPS Suprise despite revenue shock Trick or treat?
					Report	Analyst	(2)	Cazenove	Deutsche Bank
						Date	(1)	2. 10/31/06 Cazenove	3. 10/31/06 Deutsche Bank

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October 31, 2006 through November 4, 2006

Contents of	Sanofi's	10/26/06	Submission	(10)	
Did Not Say that	These May		a New Clinical Trial	6)	
No Data	from a	cal	Trial	(8)	
Submitted	No New	Clinical	Data	6	
Sanofi	• •	_	Data	(9)	
a Complete	Response to	the Approvable	Letter	(2)	
			Quote	(f)	As we highlighted in our report dated January 27, 2006 the FDA might have concerns regarding the lack of depressed patients included within the RIO studies, given Acomplia's mechanism of action on the central nervous system and depression being 2.5x more prevalent in an obese population compared to a normal population. The UK prescribing instructions state that "depressive disorders were reported in 3.2% of obese patients, or overweight patients with associated risk factor(s) treated with rimonabant 20 mg and that "these were usually mild or moderate in severity and resulted in recovery in all cases either after corrective treatment or discontinuation of imonabant and did not exhibit any differentiating characteristics compared to cases reported in the control groups". In line with the UK prescribing instructions, the incidence of psychiatric disorders appear higher than one would expect in a normal population of patients We now anticipate news flow to become marginally more positive over the next 6 months. 1. Approval of Acomplia (Q4 '06/ H1 '07). Our 2010E revenue forecast of Euro 1.2 bn assumes that Acomplia is approved as a weight loss only agent, with minimal weight independent HbA1c lowering effects. The delay to Acomplia is expected but will be a negative to sentiment. We had not forecast any significant US sales until early 2007, however at least a 3 month delay to the start of those sales now looks likely. The launch in EU is rolling out and data (SERENADE) testing Acomplia in diabetes patients (not receiving treatment) will be presented in December at the WDF. This could establish whether Acomplia can stand up as a stand alone diabetes treatment. Some may focus on the likely delay to Acomplia, however we would larguel it is not a surprise and the substantial savings in SG&A shows the financial flex of the company.
		i	Title	(3)	
	1	Report	Analyst	(2)	
			Date	Ξ	

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				a Complete	Sanofi	Submitted	No Data	Did Not Say that	Contents of
				Response to	Submitted	No New	from a	These May	Sanofi's
	Report	E		the Approvable	No New	Clinical	New Clinical	Have Been from	10/26/06
Date	Analyst	Title	Quote	Letter	Data	Data	Trial	a New Clinical Trial	Submission
(1)	(2)	(3)	(4)	(5)	(9)	(7)	(8)	(6)	(10)
4. 10/31/06	6 Dresdner Kleinwort	Sanofi-Aventis Results for Q3. EPS stronger than expected, slight	SAN has submitted a complete response to FDA on Oct 26 on Acomplia. Our best guess would be an FDA reply in April 2007 – 6 months, although earlier is a possibility. However we expect there may more clarity on the conference call.	yes	по	no	по	no	yes
		delay to Acomplia likely	The delay to Acomplia is expected but will be a negative to sentiment. We had not forecast any significant US sales until early 2007, however at least a 3 month delay to the start of those sales now looks likely. The launch in EU is rolling out and data (SERENADE) testing Acomplia in diabetes patients (not receiving treatment) will be presented in December at the WDF. This could establish whether Acomplia can stand up as a stand alone diabetes treatment.						
			Some may focus on the likely delay to Acomplia , however we would arge it is not a surprise and the substantial savings in SG&A shows the financial flex of the company.						
10/31/0	10/31/06 Dresdner Kleinwort	Sanofi-Aventis Q3 results down on last year but ahead of expectations							
10/31/0	10/31/06 Dresdner Kleinwort	Sanofi-Aventis Preview for Q3. Clarity on restructuring expected. Value still to be unlocked.	There are four questions investors would like answers to 3. Acomplia FDA approval Unfortunately, we only expect clarity on 4. restructuring charges and effects.						

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	Report	ort		Response to the Approvable	Response to Submitted the Approvable No New	d No New Clinical	from a New Clinical	These May Have Been from	Sanofi's 10/26/06
Date	Analyst	Title	Quote	Letter	Data		Trial	æ	Submission
(1)	(2)	(3)	(4)	(5)	l	 	(8)	(6)	(10)
5. 10/31.	5. 10/31/06 Exane BNP Paribas	Weak Q3 sales compensated by tough cost cutting	Acomplia's SERENADE results in diabetes will be presented early December. The complete response to the approvable letter was submitted on 26 October, which means Acomplia could still be approved by year end, but may also slip into 2007. Q3 sales were EUR11m, below our EUR30m estimate, a number that is difficult to read. SAN claims it is one of the top six UK launches, after three months on the market. We reiterate our Outperform rating and EUR31 price target (excl. US Plavix) driven by Acomplia. The key triggers remain its US approval and clinical results in diabetic patients (the SERENADE trial).	yes	00	ou	OH.	Ou Ou	yes
11/15	11/1/06 Exane BNP Parrbas	Acomplia: SERENADE while waiting for the FDA's answer	Acomplia will remain SAN's main catalyst in the near future. We anticipate positive results in diabetics in early December (the SERENADE study) but SAN is still unable to say whether the FDA's answer to its complete response will take two months or six. Acomplia's UK launch is in line with other major products but sales numbers will be tough to read over the next few quarters, as is usually the case for launches outside the US. Although the FDA's review timelines remain a moving target, we still anticipate Acomplia will be approved within this timeframe						

Sanofi-Aventis

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October 31, 2006 through November 4, 2006

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	Report			that Sanofi Submitted a Complete Response to the Approvable	that Sanofi Submitted No New	that Sanofi Submitted No New Clinical	that Sanofi Submitted No Data from a New Clinical	May Have Submitted New Data, Analysis, but Did Not Say that These May Have Been from	Nothing about the Contents of Sanofi's 10/26/06
Date	Analyst	Title	Quote	Letter	Data	Data	Trial	a New Clinical Trial	Submission
Ξ	(2)	(3)	(4)	(2)	9)	6	(8)	(6)	(10)
			Acomplia: US approval remains a moving target but the SERENADE results are likely to be positive I) Positive SERENADE results expected in early December The company made very optimistic comments on the SERENADE trial results in diabetics (obesity not an inclusion criteria) to be published on 3-7 December, which implies it already knows the data. We expect positive results for Acomplia which should allow for good reimbursements worldwide. As a reminder, our estimates include a use in obesity and diabetes with good reimbursements worldwide. We do not include potential off-label sales in cardiovascular prevention, a much larger market. 2) The FDA's review timeline remains a moving target The complete response on 26 October means the FDA must answer by 26 December 2006 ("Class 1") or 26 April 2007 ("Class 2"). Generally, the FDA would have 14 days to tell SAW whether it will be Class 1 or 2. It is still not clear to us whether SAN intends to make the FDA's answer public once it has it. To be on the safe side, we have adjusted our sales estimates for Acomplia to include a Class 2 review in our model, implying a launch in Q2 07 (versus our previous expectation of end-2006). The impact on our 2010 estimates is minimal (EUR2.0bn versus EUR2.1bn previously). 3) First market feedback: SAN's comments were positive, but numbers will be tough to read for some time. SAN is discounted by 8% to the sector's 2009 P/E multiples excluding Plavix, which we view as mostly due to the Acomplia uncertainty. The cut in the discount depends primarily on Acomplia's US approval but could be partially helped by positive SERENADE results (see above). We still believe Acomplia will be approved in the US over the next six months, and we therefore maintain our Outperform rating. As a result of our downwards earnings revisions, we have reduced our 12-month target price to EUR80 from EUR81.						

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Contonts of	Sanofi's	10/26/06	Submission	(10)	yes	ව <u>ි</u>
Did Not Say that	These May	Have Been from	a New Clinical Trial	(6)	ou	9
No Dete	from a	New Clinical	Trial	(8)	Ou Ou	2
Submitted	No New	Clinical	Data	(7)	Ou	2
Sanofi	Submitted	No New	Data	(9)	он	, ses
a Complete	Beenonse to	the Approvable	Letter	(5)	2	yes
			Quote	(4)	Although sanofi's 3Q results on October 31 met with investor expectations at the profit level, a notably weak top line and continued delay to Acomplia in US resulted in further pressure on the shares. Of greatest concern was weakness to some key brands and growth drivers, which is likely to persist: when combined with a continued delay to Acomplia in US, limited pipeline visibility and a challenging patent profile, long-term strategy continues to be a focus for investors Key Risks:FDA response on Acomplia	Delay in US approval of obesity treatment Acomplia does not bode well for its sales potential once launched No greater visibility regarding Acomplia in the USA Acomplia update Acomplia update Much of the Q3 results conference call centred on the outlook for Acomplia and management's comments failed to shed much light on visibility for the drug In the USA, Sanofi-Aventis has responded to EDA requests received at the time of the Approvable Letter in February 2006. Sanofi-Aventis submitted its response, which apparently did not chicude any additional data, on 26 October, and management is unwilling to make any predictions regarding the timing of Acomplia's approval in the USA. We would hazard a guess that full approval is likely to come in the first quarter of 2007 although the strength of the labelling may be compromised given the time being taken to come to the decision. Despite a valuation multiple that already implies a 10% discount to the sector, we remain very cautious about the outlook given the poor visibility. Despite management claims that Acomplia has enjoyed a great launch in Europe, sales so far have only reached EUR11m and there is no guarantee that the product will even make it to the market in the USA.
		rt	Title	(3)	Disappointing 3Q mix; focus is Acomplia/strategy	RUNNING INTO
		Report	Analyst	(2)	Goldman Sachs	Helvea
			Date	(1)	6. 11/1/06	7. 10/31/06

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Contents of	Sanofi's	10/26/06	Submission	(10)	yes	yes	по
Did Not Say that	These May	Have Been from	a New Clinical Trial	(6)	Ou	00	yes
No Data	from a	New Clinical	Trial	(8)	ou	01	no
Submitted	No New	Clinical	Data	(7)	ou	ou	по
Sanofi	Submitted	No New	Data	(9)	no	01	по
a Complete	Response to	the Approvable	Letter	(5)	OU	yes	yes
			Quote	(4)	Non-approval of pipeline drug, a cause for concern Sanofi-Aventis' Acomplia was approved in the UK in June 2006; however, it is still awaiting approval in the US, which is likely to be a significant market for the drug. Any delay or nonapproval of these promising drugs could severely affect the company's revenues, going forward.	It appears unlikely that Acomplia will be approved in the US before late April 2007. In the meantime, we see few catalysts for the shares and while it is cheap, we believe management credibility will hamper any share price recovery. Downgrade to HOLD Acomplia's US approval delayed until April 2007. sanofi refused to comment on the likely approval time for Acomplia in the US. What we do know is that the company received questions along with an approvable letter from the FDA in February 2006 for the treatment of Acomplia, sanofi responded to the FDA's questions with a complete response on 26 October. We believe approval is likely to take six months. What we fail to understand is why sanofi refused to comment on the FDA response time.	The first sales of Acomplia look promising, especially in the UK where the product was launched in late June and enjoys reimbursement status. Its Q3 06 sales amounted to €11m. In the US, the group submitted a full response to the FDA'sapprovable letter on 26 October 06.
		rt	Title	(3)	Generic competition and manufacturing disruptions impact top-line growth in 3Q 06	Acomplia delay?	Q3 06 results, a weak top line
		Report	Analyst	(2)	IIR Group	ING	IXIS
			Date	(1)	8. 10/31/06 IIR Group	9. 10/31/06 ING	10. 10/31/06

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October 31, 2006 through November 4, 2006

Regarding the Value Acompia in the Costantian Programment of Acompia in the Costantian Programment of Acompia in the Costantian application approval on 26 October. We believe that a six months' review is most likely, precluding a 2006 launch. We anticipate that the share price will trade at its current level, until we have seen a clarification of: 2. The approval procedure of Acompia (obesity) in the US Regarding the US launch of Acompia (obesity) in the US Regarding the US launch of Acompia (obesity) the company announced that it will receive the answer to the FDA application approval on 26 October. We believe that a six-month review is more likely than a 3-month review. In all circumstances, this precludes a 2006 launch. At a 6-month review, we may see an approval of Acomplia in April 2007, but a potential launch at mid-2007. We cannot preclude, however, that Acomplia may be subject to further delays.

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Sanofi-Aventis

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With Regard to What Sanofi Submitted to the FDA, the Analyst Said: that Sanofi

	Nothing	about the	Contents of	Sanofi's	10/26/06	Submission	(10)	e
Mav Have	Submitted New	Data, Analysis, but	Did Not Say that	These May	Have Been from	a New Clinical Trial	(6)	yes
that	Sanofi	Submitted	No Data	from a	New Clinical	Trial	(8)	OL
	that	Sanofi	Submitted	No New	Clinical	Data	(7)	yes
		that	Sanofi	Submitted	No New	Data	(9)	yes 3 [but seemingly in error]
	that Sanofi	Submitted	a Complete	Response to	the Approvable	Letter	(5)	yes
						Quote	(p)	3Q was dominated by weak sales in a number of key franchises and a lack of clarity over timetable for US Acomplia approval. Given past delays, management caution on Acomplia may be understandable but post-Plavix, the lack of clarity has not been helpful. Our working hypothesis is a 50:50 likelihood of an FDA response by end-Dee 2006. The one positive from the results was the demonstration of cost flexibility in the business. We make limited changes to forecasts as cost savings offset slower sales growth. We see EUR 65 as a key support level for the stock (EV/NPV 1.0x) but believe that positive momentum requires clarity on US Acomplia or exceptionally strong SERENADE data (3-7 Dec). On US Acomplia, the company announced that it has made a complete response to the FDA approvable letter on 26 October 2006 but would not be drawn on the implications this may have on US approval. Given this uncertainty, combined with weak sales in key franchises, the fall in the stock price is not unexpectedThe next key triggers are further clarity on US Acomplia (timing unclear) or exceptionally strong SERENADE data on Acomplia in newly-diagnosed type-2 diabetics (World Diabetes Congress, 3-7 Dec). Why the lack of clarity on US Acomplia timing? Management's comments on the conference call provided little clarity on the potential timeline for FDA approval of Acomplia in the US. On initial review, this lack of clarity appears surprising as we believe that the logistics of the next FDA steps are relatively clarr. Based on the FDA dapproval of Acomplia in the US. On initial review, this lack of clarity appears surprising as we believe that the logistics of the next FDA steps are relatively clarr. Based on the FDA dapproval of Acomplia in the US. On initial review, this lack of clarity appears surprising as we believe that the logistics of the next FDA steps are relatively clarr. Based on the FDA dapponed of Acomplia in the US. On initial review, this lack of clarity appears 2 status will lead to FDA aptorn class 2 status will lead
					rt	Title	(3)	Poor sales and no clarity on Acomplia
					Report	Analyst	(2)	11/1/06 Lehman Brothers
						Date	(1)	11/1/06

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With Regard to What Sanoff Submitted to the FDA, the Analyst Said:
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Exhibit 19

Sanofi-Aventis

Analyst Commentary Following the October 31, 2006 2:00 a.m. Earnings Conference Call

During Which Defendant Spek, in Response to a Question About Whether the Company Had Submitted Data, Said, "... As the Approvable Letter Did not Ask for New Additional Clinical Trials, Consequently it is Easier for Me to Say that We Have Not Submitted New Data in this Respect", and that Sanofi "Submitted October 26 a Complete Response to This Approvable Letter..."

9-0	عاد	יט-	H١	VI		ocument 18	38-T	Filed	1 04/30/1	2 Page 124 of 1
	Nothing	about the Contents of	Sanofi's	10/26/06	Submission					yes
May Have	Submitted New	Data, Analysis, but Did Not Say that	These May	Have Been from	a New Clinical Trial					maybe 4
that	Sanofi	Submitted No Data	from a	New Clinical	Trial					91
	that	Sanoti Submitted	No New	Clinical	Data					Qu
	•	that Sanofi	Submitted	No New	Data					91
	that Sanofi	Submitted a Complete	Response to	the Approvable	Letter					yes
					Quote	Based on Sanoff's statement that there is no new clinical data included in their Complete Response, FDA Guidelines would strongly suggest that Sanoff should expect a Class 1 review, triggering and end-December 2006 action date. Given the logistics with the FDA seem clear-cut, the key question is why is Sanoff providing little clarity on timing? We believe that there may be a number of key reasons: 1) While Sanoff acknowledges that FDA guidelines exist for Action Letter re-submissions, it is clear that the company	has had some unexpected dealys in the past 2) Interestingly, if a 14-day acknowledgement letter arrives from the FDA in November 2006, it remains unclear whether Sanoff-Aventis will make its contents public 3)It is also important to note that, while no new data were submitted to the FDA, the company did acknowledge	that it took many months to compile the Complete Response. Sanoff's caution may therefore reflect an acknowledgement that the FDA may require more than two months to review the re-filing.	Based on the available FDA guidance notes and Sanoff's statement on the content of the complete response, we believe that Acomplia deserves a Class I response with a PDUFA date of 26 December 2006. However, given the magnitude of the dataset in the response, we recognize that FDA may needed longer—either by using a Class 2 deadline or by issuing another Approvable letter in December 2006. Based on this observation, we believe there is 50:50 likelihood of a complete response by year-end 2006.	US approval of key pipeline drug Acomplia (obesity) seems likely delayed into 2Q07 and the company's response to FDA's February approvable letter does not appear to have included the SERENADE data in treatment of diabetes (presentation expected December 06) Acomplia looks delayed to 2Q07 - diabetes data year-end The company provided two key updates on Acomplia: 1) The product was re-filed with the FDA 26th October (in response to the approvable letter in February). It is unclear whether this on a 2 or 6 month review cycle but given the time taken to prepare the response we assume that the latter is more likely, delaying US approval to 2Q06 (sic) vs our current forceasts of an early 07E launch; 2) Importantly the company announced it is due to present results from the SERENADE study (investigating Acomplia as a first line treatment in type II diabetics) at the IDF (International Diabetes Federation) annual conference in Dec 06.
					Title					Little to inspire in 3Q06 results
				Report	Analyst					Метіll Lynch
					Date					13. 10/31/06

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With Regard to What Sanofi Submitted to the FDA, the Analyst Said:
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Sanofi-Aventis

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	G.	Date Analyst Title	(1) (2) (3)		11/1/06 Merrill Lynch New concerns for longer term growth		
		Quote	(†)	However this does not appear to have formed part of the re-submission filed with the FDA and believe it is unlikely to be sufficient for a type II diabetes treatment indication given it is only a 280 patient study.	Likely Acomplia delay removes near-term catalyst In our view, the US approval of Acomplia now appears unlikely until 2007, given Sanofi only completed its response in our view, the US approvable letter on October 26th. Also, disappointingly it appears that the initial US label will not contain the SERENADE data in treatment of diabetes. Assume Acomplia launch in mid-07: We now conservatively assume that Acomplia is launched in mid-07 following Sanofi's disclosure that it only responded to FDA's response letter at the end of October (discussed below)	Disappointingly, we now believe that the US approval of Acomplia now appears unlikely before 2007 and we have delayed our assumed launch by 6-months to mid 07 in our model. Sanofi revealed that it had only submitted its complete response to the TeA's approvable letter on 26 October 2006. Whilst the review time is uncertain with 2 or 6 months both possible, given the length of time taken to submit its response, we can only conclude that the response contains considerable amount of additional information which the FDA is likely to require 6 months to require 6 months to	
Submitted a Complete	Response to	tne Approvable Letter	(5)	ve it is	its response I will not 07 following	77 and we submitted ecrtain with ide that the formults of months to	
that Sanofi	• 2	No New Data	(9)				
Sanofi Submitted	No New	Cilnical Data	(7)				
Submitted No Data	from a	New Clinical Trial	(8)				
Data, Analysis, but Did Not Say that	These May	a New Clinical Trial	(6)				
about the Contents of	Sanofi's	Submission	(10)				

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Exhibit 19 Sanofi-Aventis

Analyst Commentary Following the October 31, 2006 2:00 a.m. Earnings Conference Call

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Contents of	Sanofi's	Submission	(10)	yes	yes	ои
Did Not Say that	These May	nave Been Irolli a New Clinical Trial	(6)	Ou	01	ОП
No Data	from a	Trial	(8)	Q _I	^Q	ou
Submitted	No New	Data	(7)	Ou Ou	Ou	yes
Sanofi	• 1	No New Data	(9)	оп	ОП	ОП
a Complete	Response to	the Approvable Letter	(3)	yes	yes	yes
		Quote	(4)	Despite recent US Acomplia filing, we see '06 approval as improbable. We continue to expect the FDA to grant Acomplia class II resubmission, pushing potential approval date into 2Q 2007. Initial UK script trends are encouraging. Suicides in Acomplia patients reported in Canada but "company claims event rate in placebo group significantly lower [sic] Acomplia treated patients". Outlook volatile ahead of resolution of US Acomplia approvability. Near term, events include Sanoff's SERENADE data and onset of US Lovenox trial in December. US Plavix court case scheduled to start January 22. McKesson reports generic Plavix inventory almost expired.	Refiling of Acomplia in the US, SERENADE trial results for Acomplia in Diabetic patients (December 06e) and some more visibility on the upcoming restructuring should support the share ACOMPLIA REFILED OCTOBER 26 IN US It obviously took the company longer to answer the questions by the FDA following the approvable letter in February. It is not yet clear whether the FDA will require a two or a full six month review cycle. However, on the basis of a good start in Europe SERENADE data of Acomplia in Diabetes are due December.	On Acomplia, SNY say the response to the approvable letter was submitted on Oct. 26th Risks to the SNY story include: (1) the potential that Acomplia/rimonabant is not as commercially successful as we have modeled
		Title	(3)	Sanofi-Aventis 3Q not pretty, Acomplia and Plavix outlook remains opaq	Negative Factors Largely Reflected by Share Price	SNY: Q3 EPS Quick- TakeBeats EPS But Misses Revenues
	1	Analyst	(2)	Morgan Stanley	11/2/06 Oppenheim	Prudential Equity Group, LLC.
		Date	Ξ	11/3/06	11/2/06	16. 10/31/06
		ļ	1	4.	15.	16.

Sanofi-Aventis

Analyst Commentary Following the October 31, 2006 2:00 a.m. Earnings Conference Call

During Which Defendant Spek, in Response to a Question About Whether the Company Had Submitted Data, Said, "... As the Approvable Letter Did not Ask for New Additional Clinical Trials, Consequently it is Easier for Me to Say that We Have Not Submitted New Data in this Respect", and that Sanofi "Submitted October 26 a Complete Response to This Approvable Letter..."

Nothing about the Contents of Sanofi's 10/26/06	Submission (10)			
With Regard to What Sanofi Submitted to the FDA, the Analyst Said: that that Anay Have that Sanofi Submitted Data, Data Dai Not Say that Sanofi Submitted No Data Did Not Say that Submitted No New from a These May No New Clinical New Clinical Have Been from	a New Clinical Trial (9)			
that Sanofi Submitted to the No Data from a New Clinical	Trial (8)			
What Sanoff S that Sanoff Submitted No New Clinical	Data (7)			
rith Regard to that Sanofi Submitted No New	Data (6)			
that Sanofi Submitted a Complete Response to	Letter (5)			
	Quote (4)	On lead drug rimonabant, while the company has submitted its response to the "approvable letter," we still think the timing of U.S. approval/launch is far from clear - but this appears to be increasingly built into share price	The stock continues to be plagued by investor unease over the future of rimonabant, primarily in the U.S. SNY announced that it had recently submitted its response to the February '06 approvable letter, but declined to say whether they thought it would be classified as a "Class I" or "Class II" resubmission.	Despite not supplying new clinical data in the resubmission, as the SNY finally admitted to, it is still possible—and in our opinion likely – that the review period will last 6 months. We also believe that an Advisory Committee is highly likely to be convened prior to full approval, especially with staffing changes that occurred about a year ago in the Endocrine division of FDA that will primarity be reviewing the product. And even when the product finally emerges from regulatory review, it may have enough restrictions attached to it that its commercial uptake is slow and arduous. Acomplia's commercial potential is obviously important, but what matters most in the minds of investors at present is merely getting the product approved and on the market Risks to the SNY story include: (1) the potential that Acomplia/rimonabant is not as commercially successful as we have modeled
	Title (3)	SNY: Q3 Revenues MissAnd It Wasn't Just	Because of Generic Plavix	
Report	Analyst (2)	11/1/06 Prudential Equity Group, LLC.		
	Date (1)	11/1/06		

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Exhibit 19

Analyst Commentary Following the October 31, 2006 2:00 a.m. Earnings Conference Call Sanofi-Aventis

During Which Defendant Spek, in Response to a Question About Whether the Company Had Submitted Data, Said, "... As the Approvable Letter Did not Ask for New Additional Clinical Trials, Consequently it is Easier for Me to Say that We Have Not Submitted New Data in this Respect", and that Sanofi "Submitted October 26 a Complete Response to This Approvable Letter..."

October 31, 2006 through November 4, 2006

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6	about the	Contents of	Sanofi's	10/26/06	Submission	(10)	yes	ou	
	Data, Analysis, but	Did Not Say that	These May	Have Been from	a New Clinical Trial	(6)	01	yes	
	Submitted	No Data	from a	New Clinical	Trial	(8)	Ou Ou	yes	
	Sanofi	Submitted	No New	Clinical	Data	(2)	01	yes	
	that	Sanofi	Submitted	No New	Data	(9)	Q	ou	
	Submitted	a Complete	Response to	the Approvable	Letter	(5)	yes	yes	
					Quote	(4)	Acomplia sales came to just EUR11m versus our estimate of EUR30m. This is a weak performance for an initial launch, even though few countries are involved. Sanofi-Aventis finally announced that it submitted its response to the FDA's questions on 26 October 2006. Remember that the FDA issued an approvable letter in February, and for all this time the group assured us that it was in active discussions with the FDA. It is now clear that the group will not be able to launch Acomplia in 2006. A launch in Q1 2007 may be unlikely if the group's communication on this subject remains so unclear. However, Acomplia still has some way to go in the US. Although the situation is slightly clearer than before—the group submitted its response to the FDA on 26 October—Sanoff-Aventis is still very "discrete" about its exchanges with the FDA, refusing to give any likely date for approval. Although technically approval could still be given before the end of the year, we think that the PDA is unlikely to announce its decision before February or March 2007. This is what we assume, with a launch at the start of Q2 2007.		Analyst meeting/conference call Conference call just ended and as usual the Company is not answering the most burning questions related the Acomplia approval in the US. Main surprise Last but not least, the company updated on the approval process of Acomplia/rimonabant in the US, where a complete response to the FDA was submitted on 26 October. It seems that no additional clinical data were required (no new trials asked for by the FDA), so the question is: how is it that the response took 8 months to complete and that the company could not anticipate that it would take them so long, just a couple of months ago? In our view, there are further doubts on management's credibility.
				-t	Title	(3)	Q3 results: disastrous top line, Acomplia unconvincing in Europe and management does not provide any visibility	Too Healthy!	Will things get worse? Unlikely, but managements credibility is further indented
				Report	Analyst	(2)	11/1/06 Raymond James Euro Equities	Societe Generale	Societe Generale
					Date	(1)	17. 11/1/06	18. 10/31/06	10/31/06
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October 31, 2006 through November 4, 2006

Contents of Sanofi's 10/26/06	Submission (10)				
Did Not Say that These May Have Been from	a New Clinical Trial (9)				
No Data from a New Clinical	Trial				
Submitted No New Clinical	Data (7)				
S ~	Data (6)				
a Complete Response to the Approvable	Letter (5)				
	Quote (4)	There are two events that could be positive catalysts for the share in early December: 1) a pick-up in Plavix prescriptions in the US as generic clopidogrel inventories dry out more widely, and 2) the presentation of SERENADE data (Acomplia as a monotherapy in type-2 diabetes patients) at the International Diabetes Federation meeting. They could convince the lost sceptical that Acomplia's positive effect on cardiometabolic risk factors come from the product per se and not just from weight loss. This could prove crucial to secure reimbursement.	the market is likely to remain cautious before seeing the SERENADE data in early December and a pick-up in US Plavix prescriptions.	□ Next event analysis There are two events that could be positive catalysts for the share in early December: 1) a pick- up in Plavix prescriptions in the US as generic clopidogrel inventiories dry out more widely, and 2) the presentation of SERENADE data (Acomplia as a monotherapy in type-2 diabetes patients) at the International Diabetes Federation meeting. They could convince the lost sceptical that Acomplias positive effect on cardiometabolic risk factors come from the product per se and not just from weight loss. This could prove crucial to secure reimbursement.	
	Title (3)	Fair value downgrade	Reducing FV from e90 to e85.6		Sanofi-Aventis Rating reiterated Generic clopidogrel inventories start to dry up
Report	Analyst (2)	11/2/06 Societe Generale	11/2/06 Societe Generale		Societe Generale
	Date (1)	11/2/06	11/2/06		11/3/06

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With Regard to What Sanofi Submitted to the FDA, the Analyst Said: that Sanofi

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October 31, 2006 through November 4, 2006

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Contents of	Sanofi's	10/26/06	Submission	(10)	OII		
Did Not Sav that	These May	Have Been from	a New Clinical Trial	6)	yes		
No Data	from a	New Clinical	Trial	(8)	yes		
Submitted	No New	Clinical	Data	9	по		
Sanofi	Submitted	No New	Data	9	ОП		
a Complete	Response to	the Approvable	Letter	(3)	yes		
			Quote	(4)	Acomplia complete response submitted; Apr '07 PDUFA likely SASY said it submitted a complete response to the FDA's approvable letter for Acomplia on 26 Oct. We believe a 6 month review is more likely than a 3 month review. In any event, this rules out a 2006 US launch and 6m would see the FDA response at Apr '07 with a possible launch mid-07 (we do not rule out the possibility of further delays).	Acomplia: complete response submitted but no further clarity. Sanoff-Aventis revealed it had submitted a complete response to the FDA's approvable letter for Acomplia, although did not offer much clarity on the information provided to the FDA (other than that data had not been provided from new clinical trials) and would not hazard a guess as to how long the FDA might take to review the submission. We expect a 6-month review, with risk of further delay Stock likely to be rangebound without more US Acomplia news SASY is influenced by four issues over which there is not much transparency; (1) US Acomplia; (2) US Lovenox; (3) US Plavix; and (4) a possible sell-down by substantial shareholders L'Oreal and Total. Without clarification of these, we expect the stock will remain rangebound	SASY announced that a complete response had been delivered to the FDA only last week but were not prepared to hazard a guess at how long the FDA may take to review it. Given the response was submitted several months after the approvable letter was received (in February), we believe it will take the FDA six months postabinision rather than three months to review the new information. This would put an FDA decision at around April/May 2007, with a mid-year launch, a slight delay over our previous assumption for an early Q2 launch. We think there is too much riding on the US launch of Acomplia for there to be such little transparency over even the likely review time. Without further colour, we think the stock will remain range bound. Neutral 2
		+	Title	(3)	Q3,9M'06 results miss expectations; No US Acomplia launch this year	Acomplia: a riddle wrapped in an enigma, shrouded in mystery	
		Report	Analyst	(2)	UBS Investment Research	UBS Investment Research	
			Date	Ξ	19. 10/31/06	11/1/06	
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Sanofi-Aventis

Analyst Commentary Following the October 31, 2006 2:00 a.m. Earnings Conference Call

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October 31, 2006 through November 4, 2006

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Nothing about the Contents of Sanofi's 10/26/06	Submission	(10)	yes	12
With Regard to What Sanofi Submitted to the FDA, the Analyst Said: that Sanofi that Sanofi that Sanofi that Sanofi Submitted No Data Sanofi Submitted No Data Submitted Submitted No Data Submitted No New from a These May the No New Clinical Have Been from	a New Clinical Trial	€	ио	5
that that Sanofi Submitted No Data from a New Clinical	Trial	<u>©</u>	ou	3
that Sanoff Sanoff Sabmitted No New Clinical	Data	6	по	3
Vith Regard to that Sanofi Submitted No New	Data	9	Ю	2
that Sanofi Submitted a Complete Response to	Letter	<u> </u>	yes	18
	Quote	Given stronger EPS but weaker sales outcome and our belief that Acomplia will not be launched in the US until mid-07 (unless there are further delays, which can't be ruled out), we have raised our 2006 EPS estimate from 64.90 to 65.10 (+4%, representing 8% growth over 2005) but lowered our estimate in 2007 from 65.52 to 65.52 to 65.52 to 65.52 (-3%) and lowered our 2008 estimate from 66.92 to 65.92 (-2%) Statement of Risk: The major drug in development for obesity, Acomplia, received an approvable letter from the FDA and its US launch remains uncertain.	Sanofi-Aventis has submitted a complete response letter to the FDA on Acomplia (rimonabant) on 26 October, indicating that a likely US Acomplia launch will be upcoming in Q2 2007.	Total
E.	Title	€	Mixed set of Q3 2006 results - Us Acomplia launch likely delayed until 2007	
Report	Analyst	(5)	WestLB Equity Research	
	Date	€	20. 10/31/06 WestLB Equity Research	

Notes and Sources:

This exhibit includes all uniquely-titled English-language, company-specific, non-technical, non-vaccine reports issued during the period that NERA was able to obtain from counsel or purchase from Reuters Knowledge or Thomson Investext

^{1&}quot;03 2006 Sanofi-Aventis Earnings Conference Call-Final," Voxant FD Wire, 10/31/06, "Sanoff Aventis Ads - SNY: Q3 Earnings Call @ 02:00 ET Today," Knobias, 10/31/06 9:12 a.m. ET.

 $^{^2}$ Analyst seems to mistakenly refer to 10/26/06 as the FDA action date.

³ While in one place the report says "no new data were submitted to the FDA," elsewhere it says "no new clinical data" and refers to "the magnitude of the dataset in the response.... The second and third phrases strongly suggest that the adjective

[&]quot;clinical" was inadvertently omitted from the first phrase.

^{4 &}quot;Information" may or may not refer to new data: "...given the length of time taken to submit its response, we can only conclude that the response contains considerable amount of additional information which the FDA is likely to require 6 months to review..."

Exhibit 20 Sanofi-Aventis

Analysts' Rating Following the October 31, 2006 2:00 a.m. Earnings Conference Call October 31, 2006 through November 3, 2006

	Report	
Analyst	Date ¹	Rating
(1)	(2)	(3)
1. Bear Stearns	11/1/06	Underperform
2. Cazenove	10/31/06	Underperform
3. Deutsche Bank	10/31/06	Hold
4. Dresdner Kleinwort	10/31/06	Buy
5. Exane BNP Paribas	11/1/06	Outperform
6. Goldman Sachs	11/1/06	Neutral
7. Helvea	10/31/06	Neutral
8. IIR Group	10/31/06	Buy
9. ING	10/31/06	Hold
10. IXIS	11/1/06	Add
11. Jyske Bank	11/1/06	Accumulate
12. Lehman Brothers	11/1/06	1-Overweight
13. Merrill Lynch	10/31/06	Neutral
14. Morgan Stanley	11/3/06	Overweight
15. Oppenheim	11/2/06	Buy
16. Prudential Equity Group, LLC	C. 10/31/06	Neutral Weight
17. Raymond James Euro Equities	s 11/1/06	Fair Value
18. Societe Generale	11/2/06	Buy
19. UBS Investment Research	10/31/06	Neutral 2
20. WestLB Equity Research	10/31/06	Hold

Notes and Sources:

This exhibit includes all uniquely-titled English-language, company-specific,non-technical, non-vaccine reports issued during the period that NERA was able to obtain from counsel or purchase from Reuters Knowledge or Thomson Investext.

¹ One report per analyst shown. If there are more than one report by the same analyst in the exhibit's date range, the report shown is either the earliest one (if the rating is the same across reports) or the one with the change in rating.

NERA

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Marcia Kramer Mayer, Ph.D.

Chair of Global Securities and Finance Practice and Senior Vice President

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Marcia Kramer Mayer, Ph.D. Chair of Global Securities and Finance Practice and Senior Vice President

Education

Harvard University

Ph.D., Economics, 1982 M.A., Economics, 1969

Stanford University

A.B., with Great Distinction, Economics, 1967

Professional Experience

2012- 2000- 1996-2000 1992-1996	NERA Economic Consulting Chair of Global Securities and Finance Practice Senior Vice President Vice President Senior Consultant
	American Stock Exchange, Inc.
1990-1992	Vice President, Research
1984-1990	Vice President, Marketing Research
1983-1984	Director, Marketing Research
1980-1983	Manager, Financial Research
1975-1980	State University of New York at Stony Brook Lecturer in Medical Economics, Department of Community Medicine, School of Medicine
1974-1975	Swarthmore College Instructor in Economics
1970-1971	National Bureau of Economic Research, Inc. Senior Research Analyst
1968	Charles River Associates Research Assistant

Marcia Kramer Mayer, Ph.D., Ph.D.

Testimony (Four Years)

Case Name	Court	Type of Testimony*, Date
Kenneth McGuire and David Wilczynki, et al., v. Dendreon Corporation, Mitchell Gold, and David Urdal, Case C07-800 MJP	U.S. District Court, W.D. of Washington	Deposition, 22 June 2010
In re Parmalat Securities Litigation, Case No. 04 MC 1633; Food Holdings Limited and Dairy Holdings Limited, et al., v. Bank of America Corporation, et al., Case 05 CV 9934	U.S. District Court, S.D.N.Y	Court/Oral, 15 September 2009 Court/Written, 17, August 2009

Party that retained Dr. Mayer is shown in bold

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^{*} It should be noted that a Court appearance or deposition may have been preceded by an Affidavit, Declaration, and/or Report

Marcia Kramer Mayer, Ph.D., Ph.D.

Publications (10 Years)

(with Douglas J. Clark) "Anatomy of a Merger Litigation," boardmember.com, 6 February 2012, and nera.com, 4 April 2012.

(with Paul Hinton) "Crowdsourcing Fraud Detection: Using Collective Wisdom to Expose the Next Madoff," NERA working paper, 9 August 2010.

"Multiple-Source Reporting: What Works for Tax Fraud Could Work for Ponzi Schemes," Kroll Global Fraud Report, Annual Edition 2009/2010, pp. 32-33.

"Ponzi Scheme Detection: How the SEC Can Catch the Next Thief," NERA Economic Consulting Working Paper, 3 August 2009.

(with Chantale LaCasse, Arun Sen and Elaine Buckberg), "Buying the Bad Stuff: Implementation Considerations for the Paulson Plan," September 2008, NERA website.

(with Cory Hohnbaum, King & Spalding LLP) "A Key Ruling on Materiality in Insider Trading Cases," September 2008, *Securities Law360*, NERA website.

"Case Closed: NERA's Role in *Securities and Exchange Commission v. John F. Mangan, Jr.*, Economic Analysis in Litigation," September 2008, NERA website.

(with Fernando Avalos) "Dealer Participation on the New York Stock Exchange and Nasdaq," May 2002, NERA website.

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Appendix 2 Sanofi-Aventis Materials Considered

Pleadings

- First Amended Complaint for Violation of Securities Laws, July 28, 2010
- Memorandum of Law in Support of Defendants' Motion to Dismiss the Amended Complaint, September 27, 2010
- Memorandum Decision and Order, March 30, 2011
- Lead Plaintiff New England Carpenters Guaranteed Annuity Fund and Hawaii Annuity Trust for Operating Engineers'
 Memorandum in Support of Motion for Class Certification, November 11, 2011
- Declaration of Harry Dow on Behalf of the New England Carpenters Guaranteed Annuity Fund in Support of Plaintiffs' Motion for Class Certification, November 11, 2011
- Declaration of Ryan Ilacqua on Behalf of Hawaii Annuity Trust for Operating Engineers in Support of Plaintiffs' Motion for Class Certification, November 11, 2011
- Declaration of Trig R. Smith in Support of Plaintiffs' Motion for Class Certification, November 11, 2011
- Defendants' Opposition to Plaintiffs' Objection to Magistrate Judge Maas' November 15 Order Denying Plaintiffs'
 Motion to Compel Documents Responsive to Request 43(b) of Plaintiffs' First Request for Reproduction of
 Documents, December 19, 2011
- Declaration of John Felitti in Support of Defendants' Opposition to Plaintiffs' Objection to Magistrate Judge Maas' November 15 Order Denying Plaintiffs' Motion to Compel Documents Responsive to Request 43(b) of Plaintiffs' First Request for Reproduction of Documents, December 19, 2011
- Declaration of Kevin A. Brennan in Support of Defendants' Opposition to Plaintiffs' Objection to Magistrate Judge Maas' November 15 Order Denying Plaintiffs' Motion to Compel Documents Responsive to Request 43(b) of Plaintiffs' First Request for Reproduction of Documents, December 19, 2011
- Declaration of Matthew C. Vogele in Support of Defendants' Opposition to Plaintiffs' Objection to Magistrate Judge Maas' November 15 Order Denying Plaintiffs' Motion to Compel Documents Responsive to Request 43(b) of Plaintiffs'
 First Request for Reproduction of Documents, December 19, 2011
- Transcript of Hearing in front of Judge Daniels, January 3, 2012
- Lead Plaintiff New England Carpenters Guaranteed Annuity Fund and Hawaii Annuity Trust for Operating Engineers'
 Memorandum in Support of Renewed Motion for Class Certification, February 1, 2012
- Declaration of Harry Dow on Behalf of New England Carpenters Guaranteed Annuity Fund in Support of Renewed Motion for Class Certification, February 1, 2012
- Declaration of Ryan Ilacqua on Behalf of Hawaii Annuity Trust for Operating Engineers in Support of Renewed Motion for Class Certification, February 1, 2012
- Declaration of Trig R. Smith on Behalf of Lead Plaintiff New England Carpenters Guaranteed Annuity Fund and Hawaii Annuity Trust for Operating Engineers' Renewed Motion for Class Certification, February 1, 2012
- Declaration of Susanne Trimbath, Ph.D in Support of Lead Plaintiff New England Carpenters Guaranteed Annuity Fund and Hawaii Annuity Trust for Operating Engineers' Renewed Motion for Class Certification, February 1, 2012

Data on Sanofi-Aventis

- Daily price (high, low, close) and volume of Sanofi ADS from FactSet Research Sytems, Inc.
- Daily price (close) and volume of Sanofi ADS and ordinary shares from Bloomberg, L.P.
- Sanofi ADS and ordinary shares index weights from Bloomberg, L.P.
- Trades and quotes in Sanofi ADS from TAQ from June 11 to June 14, 2007

Appendix 2 Sanofi-Aventis Materials Considered

- Press releases from Sanofi's website
- Sanofi press releases and conference call transcripts from Factiva, Inc.
- News stories cited in the Declaration, obtained from Factiva, Inc.
- News stories from search for suicid* and (Sanofi* or rimonabant or Zimulti or Acomplia) from Factiva, Inc.
- Sanofi analyst reports cited in the Declaration, obtained from counsel, Reuters Knowledge and Thomson Investext
- FDA Briefing Document for the June 13, 2007 Rimonabant Advisory Committee Meeting, posted on FDA's website on June 11, 2007
- Sponsor Briefing Document for the June 13, 2007 Rimonabant Advisory Committee Meeting, posted on FDA's website on June 11, 2007
- June 13, 2007 Rimonabant Advisory Committee Meeting written transcript, audio transcript, and presentation slides
- Communications between Sanofi and the FDA, SA-00021871, SA-00022050, SA-00022566, SA-00022572, SA-00103169, SA-00183719, provided by counsel
- Rimonabant Approvable Letter from the FDA, signed February 17, 2006, SA-00103528-37, provided by counsel
- Boston Partners emails, A00001-4 & A00009, provided by counsel

Additional Data

- Daily closing values of various indices from Bloomberg, L.P.
- Entire set of analyst reports in my posession (which may include duplicates, industry reports, reports not in English, reports on companies other than Sanofi, and reports from outside the period January 1, 2006 through June 30, 2007) used to perform electronic searches, consisting of (a) the initial set of analyst reports provided to me by counsel; (b) additional reports known to have been published February 24-28, 2006, October 31-November 4, 2006, or June 11-June 17, 2007; (c) additional reports sufficient to ensure that we had at least one report (if extant) by each of the 38 analysts from each of 1H2006, 2H2006, and 1H 2007 (but before June 11, 2007); (d) additional reports sufficient to ensure that for each analyst for whom we had a report issued from June 11 through June 17, 2007, we had that analyst's last report published prior to June 11, 2007; and (e) the approximately 1,470 reports that were produced in this litigation pursuant to subpoenas from Plaintiffs and Defendants before March 19, 2012 by the following analysts: Cowen & Co., Exane BNP Paribas, Goldman Sachs, Morgan Stanley, Prudential Equity Group, Raymond James, Societe Generale, and UBS Investment Research. Reports that were not obtained from counsel were purchased via Thomson Investext or Reuters Knowledge.

Court Decisions, Expert Reports and Declarations

- Berks County Employees' Retirement Fund v. First American Corp., 734 F. Supp. 2d 533 (S.D.N.Y. 2010)
- Castaneda v. Partida, 430 U.S. 482, 97 S.Ct. 1272 (1977)
- Goldkrantz v. Griffin, 1999 WL 191540, (S.D.N.Y. Apr. 6, 1999)
- In re American International Group, Inc Securities Litigation, 265 F.R.D. 157 (S.D.N.Y. Feb. 22, 2010)
- In re Executive Telecard, 979 F. Supp. 1021 (S.D.N.Y. Oct. 16, 1997)
- In re Moody's Corporation Securities Litigation, 274 F.R.D. 480 (S.D.N.Y. March. 31, 2011)
- In re Seagate Tech II Sec. Litig., 843 F. Supp. 1341, (N.D. Cal. Feb. 11, 1994)
- In re SLM Corp. Securities Litigation, Master File No. 08 Civ. 1029 (WHP), 2012 BL 15101 (S.D.N.Y. Jan. 24, 2012)
- Declaration of Dr. Kelly Posner, dated April 24, 2012

Appendix 2 Sanofi-Aventis Materials Considered

Academic Literature

- Alexander, Janet Cooper, The Value of Bad News, 41 UCLA L. Rev. 1421 (1994)
- Bradford Cornell and R. Gregory Morgan, *Using Finance Theory to Measure Damages in Fraud on the Market Cases*, 37 UCLA L. Rev. 883-924 (1990)
- Cornell, Bradford, and R. Gregory Morgan, *Using Finance Theory to Measure Damages in Fraud on the Market Cases*, 37 UCLA L. Rev. (1990)
- Cox, Alan J., and Jonathan Portes, *Mergers in Regulated Industries: The Uses and Abuses of Event Studies*, 14 Journal of Regulatory Economics, Kluwer Academic Publishers (1998)
- Daniel R. Fischel, *Use of Modern Finance Theory in Securities Fraud Cases Involving Actively Traded Securities*, 38 Bus. Law. 1-20 (Nov. 1982)
- David H. Kaye and David A. Freedman, *Reference Guide on Statistics*, Federal Judicial Center's Reference Manual on Scientific Evidence, 3rd ed., 2011, pp 211-302.
- David I. Tabak & Frederick C. Dunbar, *Materiality and Magnitude: Event Studies in the Courtroom*, Litigation Services Handbook: The Role of the Financial Expert, John Wiley & Sons, Inc., 3rd ed., 2001, Chapter 19, pp. 2-3
- Dmitry Krivin, Robert Patton, Erica Rose, and David Tabak, *Determination of the Appropriate Event Window Length in Individidual Stock Event Studies*, NERA Economic Consulting, November 4, 2003.
- Eugene F. Fama, Lawrence Fisher, Michael C. Jensen and Richard Roll, *The Adjustment of Stock Prices to New Information*, International Economic Review, Vol. 10, No. 1 (Feb. 1969)
- Finkelstein, Jared T., Note, Rule 10b-5 Damage Computation: Application of Financial Theory to Determine Net Economic Loss, 51 Fordham L. Rev. 838 (1983)
- Fischel, Daniel R., *Use of Modern Finance Theory in Securities Fraud Cases Involving Actively Traded Securities*, 38 Bus. Law. 1 (1982)
- Janet Cooper Alexander, The Value of Bad News in Securities Class Actions, 41 UCLA L. Rev. 1421-1469 (1993-1994)
- Jonathan R. Macey, Geoffrey P. Miller, Mark L. Mitchell, & Jeffry M. Netter, *Lessons From Financial Economics: Materiality, Reliance, and Extending The Reach of Basic v. Levinson*, 77 Va. L. Rev. 1017-1049 (1991)
- Koslow, Jon, Note, Estimating Aggregate Damages in Class Action Litigation Under Rule 10b-5 for Purposes of Settlement, 59 Fordham L. Rev. 811 (1991)
- Leas, Philip J., Note, *The Measure of Damages in Rule 10b-5 Cases Involving Actively Traded Securities*, 26 Stan. L. Rev. 371 (1974)
- Macey, Jonathan R. et al., Lessons from Financial Economics: Materiality, Reliance, and Extending the Reach of Basic v. Levinson, 77 Va. L. Rev. 1017 (1991)
- MacKinlay, A. Craig, Event Studies in Economics and Finance, 35 Journal of Economic Literature (March 1997)
- Mark L. Mitchell & Jeffry M. Netter, *The Role of Financial Economics in Securities Fraud Cases: Applications at the Securities and Exchange Commission*, 49 Bus. Law. 545-590 (1993-1994)
- Mitchell, Mark L., and Jeffry M. Netter, *The Role of Financial Economics in Securities Fraud Cases: Applications at the Securities and Exchange Commission*, 49 Bus. Law. (1994)

Appendix 3 Sanofi-Aventis

Analyst Firms Issuing a Report on Sanofi At Any Point Between January 1, 2006 and June 30, 2007

Analyst Firm 1. Ahorro Corporacion Financiera S.V.B 2. Aurel BGC (Aurel Leven)¹ 3. Bank of America 4. Barclays Capital (Lehman Brothers)² 5. Bear Stearns 6. Bernstein Research 7. Cazenove 8. Cheuvreux 9. Citigroup 10. Cowen and Co. (SG Cowen)³ 11. Credit Suisse 12. Deutsche Bank 13. Dresdner Kleinwort 14. DZ Bank AG 15. Exane BNP Paribas 16. Financiele Diensten Amsterdam Bv (FDA) 17. Goldman Sachs 18. Helvea 19. HSBC Global Research 20. IIR Group 21. ING 22. JP Morgan 23. Jyske Bank 24. Kepler 25. Leerink Swann 26. Macquarie (Oppenheim)⁴ 27. Merrill Lynch 28. Morgan Stanley 29. MorningStar 30. NATIXIS (NATEXIS or IXIS)⁵ 31. ODDO 32. Prudential Equity Group, LLC. 33. Raymond James Euro Equities 34. RBS (ABN AMRO)⁶ 35. Redburn Partners LLP 36. Societe Generale

37. UBS Investment Research38. WestLB Equity Markets

Appendix 3 Sanofi-Aventis

Analyst Firms Issuing a Report on Sanofi At Any Point Between January 1, 2006 and June 30, 2007

Notes and Sources:

Analyst firm list includes all analyst firms who we know to have published a uniquely-titled, English-language, company-specific report during the period. The list is based on a unique list of such reports that NERA compiled from all reports obtained from counsel or available for purchase from Reuters Knowledge or Thomson Investext. In the case of identically-titled reports of this description by the same analyst, one for the US and the other for the European ticker, the list includes the earlier-dated report or, if both have the same date, the report for the European ticker. The list excludes: a MedTrack report listing vaccines, reports from Life Science Analytics, Episcom Healthcare Intelligence, and Euromonitor Journals that do not render a recommendation or opinion, but rather state already public information, and technical reports by TheStreet.com Ratings and RiskMetrics Group. If an analyst firm was acquired or changed name, the current name is listed, followed by its previous name in parenthesis, unless both parties published reports independently during the relevant period.

- ¹ In October 2006, BCG partners acquired Aurel Leven and created Aurel BCG.
- ² In September 2008, Barclays purchased Lehman Brothers, which had filed for bankruptcy.
- Operated as SG Cowen, a unit under Societe Generale until July 2006, when it was spun off in an IPO and renamed itself Cowen and Company
- ⁴ Oppenheim was acquired by Macquarie in February 2010
- ⁵ In November 2006, Natixis was formed from the merger of Natexis and Ixis.
- ⁶ In February 2010, ABN AMRO Bank N.V. changed its legal name to The Royal Bank of Scotland N.V.

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